IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
GREAT FALLS DIVISION

ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY, *Plaintiffs*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency, *Defendants*.	Case No.: 4:21-cv-00003-BMM-JTJ The Honorable Brian Morris, Chief Judge

DECLARATION OF DEEPAK GUPTA

I, Deepak Gupta, declare as follows:

1. I am a member in good standing of the bar of the District of Columbia and am submitting this declaration in support of the plaintiffs' motion for partial summary judgment. The statements in this declaration are based on my personal knowledge and information obtained in the course of my research for this case.

2. The document attached as Exhibit A is an authentic copy of the Environmental Protection Agency's (EPA) final rule entitled Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and

Influential Scientific Information. It was published in Volume 86, No. 3 of the Federal Register on January 6, 2021.

3. The document attached as Exhibit B is an authentic copy of the EPA Science Advisory Board's letter to EPA Administrator Andrew Wheeler, dated April 24, 2020, concerning the scientific and technical basis for the then-Proposed Rule entitled Strengthening Transparency in Regulatory Science.

4. The document attached as Exhibit C is an authentic copy of an official Differing Scientific Opinion authored by Dr. Thomas Sinks, former Director of the EPA's Office of the Science Advisor, as published by the New York Times on November 27, 2020. *See* Lisa Friedman, E.P.A.'s Final Deregulatory Rush Runs Into Open Staff Resistance, N.Y. Times (Nov. 27, 2020), https://perma.cc/8N3C-3PJR.

5. The document attached as Exhibit D is an authentic copy of the comments of the Environmental Defense Fund on EPA's supplemental notice of proposed rulemaking, submitted May 18, 2020.

6. The document attached as Exhibit E is an authentic copy of a comment to EPA's proposed rule, submitted May 18, 2020, by 39 of the nation's top scientific, public-health, medical, and academic institutions—including the American Association for the Advancement of Science, the world's largest scientific society.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

/s/ Deepak Gupta
Dated: January 11, 2021 Deepak Gupta

Exhibit A

amount, instead of electing a direct rollover of the remaining account balance.

(*2*) The amount of the distribution received by Employee A is $10,000 ($3,000 relating to the plan loan offset and $7,000 relating to the cash distribution). Because the amount of the $3,000 plan loan offset amount attributable to the loan is included in determining the amount of the eligible rollover distribution to which withholding applies, withholding in the amount of $2,000 (20 percent of $10,000) is required under section 3405(c). The $2,000 is required to be withheld from the $7,000 to be distributed to Employee A in cash, so that Employee A actually receives a cash amount of $5,000.

(*3*) The $3,000 plan loan offset amount is a qualified plan loan offset amount within the meaning of paragraph (a)(2)(iii)(B) of this section. Accordingly, Employee A may roll over up to the $3,000 qualified plan loan offset to an eligible retirement plan within the period that ends on the Employee A's tax filing due date (including extensions) for the taxable year in which the offset occurs. In addition, Employee A may roll over up to $7,000 (the portion of the distribution that is not related to the offset) within the 60-day period provided in section 402(c)(3).

(E) *Example 5.* (*1*) The facts are the same as in paragraph (a)(2)(v)(D) of this section (*Example 4*), except that the $7,000 distribution to Employee A after the offset consists solely of employer securities within the meaning of section 402(e)(4)(E).

(*2*) No withholding is required under section 3405(c) because the distribution consists solely of the $3,000 plan loan offset amount and the $7,000 distribution of employer securities. This is the result because the total amount required to be withheld does not exceed the sum of the cash and the fair market value of other property distributed, excluding plan loan offset amounts and employer securities.

(*3*) Employee A may roll over up to the $7,000 of employer securities to an eligible retirement plan within the 60-day period provided in section 402(c)(3). The $3,000 plan loan offset amount is a qualified plan loan offset amount within the meaning of paragraph (a)(2)(iii)(B) of this section. Accordingly, Employee A may roll over up to the $3,000 qualified plan loan offset amount to an eligible retirement plan within the period that ends on Employee A's tax filing due date (including extensions) for the taxable year in which the offset occurs.

(F) *Example 6.* (*1*) Employee B, who is age 40, has an account balance in Plan Z. Plan Z provides for no after-tax employee contributions. In 2022, Employee B receives a loan from Plan Z, the terms of which satisfy section 72(p)(2), and which is secured by elective contributions subject to the distribution restrictions in section 401(k)(2)(B).

(*2*) Employee B fails to make an installment payment due on April 1, 2023, or any other monthly payments thereafter. In accordance with § 1.72(p)–1, Q&A–10, Plan Z allows a cure period that continues until the last day of the calendar quarter following the quarter in which the required installment payment was due (September 30, 2023). Employee B does not make a plan loan installment payment during the cure period. On September 30, 2023, pursuant to section 72(p)(1), Employee B is taxed on a deemed distribution equal to the amount of the unpaid loan balance. Pursuant to § 1.402(c)–2, Q&A–4(d), the deemed distribution is not an eligible rollover distribution.

(*3*) Because Employee B has not severed from employment or experienced any other event that permits the distribution under section 401(k)(2)(B) of the elective contributions that secure the loan, Plan Z is prohibited from executing on the loan. Accordingly, Employee B's account balance is not offset by the amount of the unpaid loan balance at the time of the deemed distribution. Thus, there is no distribution of an offset amount that is an eligible rollover distribution on September 30, 2023.

(G) *Example 7.* (*1*) The facts are the same as in in paragraph (a)(2)(v)(F) of this section (*Example 6*), except that Employee B has a severance from employment on November 1, 2023. On that date, Employee B's unpaid loan balance is offset against the account balance on distribution.

(*2*) The plan loan offset amount is not a qualified plan loan offset amount. Although the offset occurred within 12 months after Employee B severed from employment, the plan loan does not meet the requirement in paragraph (a)(2)(iii)(B) of this section (that the plan loan meet the requirements of section 72(p)(2) immediately prior to Employee B's severance from employment). Instead, the loan was taxable on September 30, 2023 (prior to Employee B's severance from employment on November 1, 2023), because of the failure to meet the level amortization requirement in section 72(p)(2)(C). Accordingly, Employee B may roll over the plan loan offset amount to an eligible retirement plan within the 60-day period provided in section 402(c)(3)(A) (rather than within the period that ends on Employee B's tax filing due date (including extensions) for the taxable year in which the offset occurs).

(b)(1) *Q–2.* When are the rules in this section applicable to plan loan offset amounts, including qualified plan loan offset amounts?

(2) *A–2.* The rules provided in paragraph (a) of this section are applicable to plan loan offset amounts, including qualified plan loan offset amounts, treated as distributed on or after January 1, 2021. However, taxpayers (including a filer of a Form 1099–R) may choose to apply the regulations in this section with respect to plan loan offset amounts, including qualified plan loan offset amounts, treated as distributed on or after August 20, 2020.

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

Approved: December 1, 2020.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2020–27151 Filed 1–5–21; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 30

[EPA–HQ–OA–2018–0259; FRL–10019–07–ORD]

RIN 2080–AA14

Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action establishes how the Environmental Protection Agency (EPA) will consider the availability of dose-response data underlying pivotal science used in its significant regulatory actions and influential scientific information. When promulgating significant regulatory actions or developing influential scientific information for which the conclusions are driven by the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect, the EPA will give greater consideration to studies where the underlying dose-

response data are available in a manner sufficient for independent validation. This action also requires the EPA to identify and make publicly available the science that serves as the basis for informing a significant regulatory action at the proposed or draft stage to the extent practicable; reinforces the applicability of peer review requirements for pivotal science; and provides criteria for the Administrator to exempt certain studies from the requirements of this rulemaking.

DATES: This final rule is effective on January 6, 2021.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OA–2018–0259. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form in the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours are 8:30 a.m. to 4:30 p.m., Monday through Friday (except Federal Holidays). Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bennett Thompson, Office of Science Advisor, Policy and Engagement (8104R), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–1071; email address: *osp_staff@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. General Information

A. Does this action apply to me?

This final rule does not regulate any entity outside the EPA. Rather, the requirements modify the EPA's internal procedures regarding the transparency of pivotal science underlying significant regulatory actions [1] and influential scientific information. However, the Agency recognizes that any entity interested in the EPA's regulations may be interested in this final rule. For example, this final rule may be of interest to entities that conduct research or another scientific activity that is likely to be relevant to the EPA's regulatory activity or development of influential scientific information. This rule has no retrospective effect on either final significant regulatory actions or influential scientific information.

[1] Consistent with OMB guidance, this rule would not apply to the following regulatory actions: Individual party adjudications, enforcement activities, site-specific actions, or permit proceedings.

B. What action is the Agency taking?

The EPA is issuing this final rule to help strengthen the transparency of the dose-response data underlying certain EPA actions and to set the overarching structure and principles for transparency of pivotal science in significant regulatory actions and influential scientific information. This rule has a much narrower scope than the 2018 proposed rule (Ref. 5) and the 2020 supplemental notice of proposed rulemaking (Ref. 7). The rule describes how the EPA will determine the consideration to afford pivotal science of the EPA's significant regulatory actions and influential scientific information for which the conclusions are driven by the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect based on the availability of the underlying dose-response data and other applicable factors. This rule builds upon prior EPA actions in response to Government-wide data access and sharing policies.

First, the EPA is requiring that, when promulgating significant regulatory actions or developing influential scientific information, the Agency will determine which studies constitute pivotal science and give greater consideration to those studies determined to be pivotal science for which the underlying dose-response data are available in a manner sufficient for independent validation.

Second, the EPA is establishing provisions for how the requirements of this part will apply. This rule sets the overarching structure and principles for transparency of pivotal science in significant regulatory actions and influential scientific information. The final rule provides that if implementing the rule results in any conflict between this rule and the environmental statutes that the EPA administers, and their implementing regulations, this rule will yield and the statutes and regulations will be controlling.

Third, this rule requires that the EPA shall clearly identify all science that serves as the basis for informing a significant regulatory action. The EPA shall make all such science that serves as the basis for informing a significant

regulatory action publicly available to the extent practicable using standards for protecting identifiable information.

Fourth, the EPA is establishing requirements for the independent peer review of pivotal science.

Fifth, the EPA is finalizing a provision that provides criteria for the Administrator to consider when granting case-by-case exemptions to the requirements of this rule.

The EPA is also defining the following terms for the purposes of this rule: ''data,'' ''dose-response data,'' ''independent validation,'' ''influential scientific information,'' ''pivotal science,'' ''publicly available,'' ''reanalyze,'' ''science that serves as the basis for informing a significant regulatory action,'' and ''significant regulatory actions.''

Finally, the EPA intends to issue implementation guidelines that will help execute this final rule consistently across programs. This may include the process for designating key studies as pivotal science, documenting the availability of dose-response data, and requesting an Administrator's exemption.

C. What is the Agency's authority for taking this action?

The EPA is authorized to issue this rule under its authority to promulgate housekeeping regulations governing its internal affairs (hereinafter, ''housekeeping authority''). This final rule describes how the EPA will determine the consideration to afford pivotal science of the EPA's final significant regulatory actions and influential scientific information based on the availability of the underlying dose-response data and other applicable factors. This rule exclusively pertains to the internal practices of the EPA and does not regulate the conduct or determine the rights or obligations of any entity outside the Federal Government.

The Federal Housekeeping Statute (5 U.S.C. 301) provides that ''[t]he head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.'' As the Supreme Court discussed in *Chrysler Corp.* v. *Brown,* the intended purpose of section 301 was to grant early Executive departments the authority ''to govern internal departmental affairs.'' [2] As the Supreme Court further explained, section 301 authorizes ''what the [Administrative Procedure Act] terms 'rules of agency organization, procedure or practice' as opposed to substantive rules.'' [3]

While the EPA is not one of the ''Executive departments'' referred to in 5 U.S.C. 101, the EPA gained housekeeping authority equivalent to that granted to Executive departments in section 301 through the Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970), which created the EPA. The Reorganization Plan established the Administrator as ''head of the agency,'' transferred functions and authorities of various agencies and Executive departments to the EPA, and gave the EPA the authority to promulgate regulations to carry out the transferred functions.

Section 2(a)(1)–(8) of the Reorganization Plan transferred to the EPA functions previously vested in several agencies and Executive departments including the Departments of the Interior and Agriculture. Section 2(a)(9) also transferred so much of the functions of the transferor officers and agencies ''as is incidental to or necessary for the performance by or under the Administrator of the functions transferred'' and provided that ''[t]he transfers to the Administrator made by this section shall be deemed to include the transfer of [ ] authority, provided by law, to prescribe regulations relating primarily to the transferred functions.'' The Federal Housekeeping Statute was existing law at the time the Reorganization Plan was enacted. Further, the Reorganization Plan does not limit the authority to promulgate regulations only to the transferred functions, but rather it transfers all authority that ''relate[s]'' to the transferred functions. Housekeeping authority is ancillary to the transferred functions because it allows the EPA to establish standard, internal procedures that are necessary to carry out and support those functions. Accordingly, the concomitant Federal housekeeping authority to issue procedural rules was transferred to the EPA.

The Office of Legal Counsel has opined that the Reorganization Plan ''convey[s] to the [EPA] Administrator all of the housekeeping authority available to other department heads under section 301'' and demonstrates that ''Congress has vested the Administrator with the authority to run EPA, to exercise its functions, and to issue regulations incidental to the performance of those functions.'' [4]

Courts have recognized the EPA as an agency with Federal housekeeping authority. The U.S. Court of Appeals for the Second Circuit, in *EPA* v. *General Elec. Co.,* 197 F.3d 592, 595 (2nd Cir. 1999), found that ''the Federal Housekeeping Statute, 5 U.S.C. 301, authorizes government agencies such as the EPA to adopt regulations regarding 'the custody, use, and preservation of [agency] records, papers, and property.' '' The U.S. Court of Appeals for the Fourth Circuit, in *Boron Oil Co.* v. *Downie,* 873 F.2d 67, 69 (4th Cir. 1989), held that the district court had exceeded its jurisdiction when it had compelled testimony contrary to duly promulgated EPA regulations, which the EPA argued were authorized by section 301. The Second and Fourth Circuits did not directly address whether the EPA was an ''Executive department,'' but rather recognized that the EPA has the authority to issue regulations governing its internal affairs and assumed that authority comes from section 301. Indeed, if the EPA did not possess housekeeping authority, the EPA would not be able to efficiently carry out its daily functions, which would in turn compromise the EPA's ability to exercise its duties as a Federal regulatory agency.

On April 30, 2018, the EPA published the Strengthening Transparency in Regulatory Science Proposed Rulemaking (''2018 proposed rule,'' Ref. 5). The 2018 proposed rule cites as authority several environmental statutes that the EPA administers: The Clean Air Act (CAA); the Clean Water Act (CWA); the Safe Drinking Water Act (SDWA); the Resource Conservation and Recovery Act (RCRA); the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Emergency Planning and Community Right-To-Know Act (EPCRA); and the Toxic Substances Control Act (TSCA). Subsequently, on May 25, 2018, the EPA published a document extending the comment period and announced a public hearing on the 2018 proposed rule to be held on July 18, 2018 (Ref. 6). That document identified 5 U.S.C. 301 as a source of authority in addition to those statutes cited in the 2018 proposed rule.

On March 18, 2020, in the **Federal Register** at 85 FR 15396, the EPA

[2] *Chrysler Corp.* v. *Brown,* 441 U.S. 281, 309 (1979).

[3] *Id.* at 310.

[4] Authority of EPA to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Government Personal Property, 32 O.L.C. 79, 2008 WL 4422366 at *4 (May 28, 2008) (''OLC Opinion'').

published the Strengthening Transparency in Regulatory Science Supplemental Notice of Proposed Rulemaking (''2020 SNPRM,'' Ref. 7), in which the EPA clarified some of the citations in the 2018 proposed rule (Ref. 5). However, because this is purely a procedural rule, the EPA is not relying on any substantive environmental statutes as authority.

This action is a procedural rule within the scope of the EPA's housekeeping authority. As the Supreme Court explained in *Chrysler Corp.,* rules of internal agency management are considered procedural rules as opposed to substantive rules under the APA.[5] Even if there could be downstream practical effects on the voluntary behavior of outside parties and on outside parties' interactions with the EPA, such impacts do not render this procedural rule substantive. (See *American Hosp. Ass'n* v. *Bowen,* 834 F.2d 1037, 1051 (D.C. Cir. 1987)—''[A]gency rules that impose 'derivative,' 'incidental,' or 'mechanical' burdens upon regulated individuals are considered procedural, rather than substantive.''). As the Supreme Court explained in *Chrysler Corp.,* ''the central distinction among agency regulations found in the APA is that between 'substantive rules' on the one hand and 'interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice on the other.' ''[6] The Supreme Court further clarified that unlike procedural rules, substantive rules have legal force and effect on individual rights and obligations, and noted that whether a rule affects individual rights and obligations is an ''important touchstone'' for distinguishing substantive rules from other types of rules.[7] This final rule does not regulate the rights and obligations of any party outside of the EPA let alone have legal force and effect on them. Any incidental impacts on voluntary behavior outside of the EPA do not render this a substantive rule.

Some public commenters asserted that the EPA lacks the authority under the substantive environmental statutes that it administers to promulgate this rule. However, the EPA is relying exclusively on its housekeeping authority to promulgate this purely procedural rule. In this final procedural rule, the EPA does not interpret or apply provisions of a particular statute or statutes that it administers. The EPA will undertake such efforts in forthcoming actions, which will be either statute-specific science transparency regulations or programmatic regulations implementing this procedural rule. Some of these subsequent actions will be substantive rules issued under the associated environmental statutes and will be subject to judicial review. In this action, the EPA is finalizing a rule of internal agency procedures, including how the Agency will consider the availability of dose-response data underlying pivotal science used in its significant regulatory actions and influential scientific information for independent validation.

Some public commenters nonetheless took the position that this rule is substantive because it will affect the Agency's interactions with regulated parties. First, and as discussed above, this final rule does not regulate any party outside of the EPA but rather exclusively governs the EPA's internal process for determining the consideration to afford pivotal science with respect to certain actions. This rule does not require any researcher or other outside entity to provide data or models to the EPA. Nor does the rule categorically exclude studies—even studies where the underlying dose-response data are not available for independent validation—and therefore any incidental impact on researchers who are developing science and deciding whether to make the underlying dose-response data available is negligible. Instead, it governs internal agency procedures for determining the consideration to afford various studies according to factors that include data availability. In doing so, the final rule provides greater transparency on the consideration the EPA will give pivotal science where the underlying dose-response data are or are not available for independent validation.

Certain commenters stated that the final rule is substantive because they asserted it imposes burdens on scientists who endeavor to have their research considered by the EPA when it makes regulatory decisions or develops influential scientific information. The EPA notes, however, that procedural rules do not alter the rights or interests of parties but they ''may alter the manner in which the parties present themselves or their viewpoints to the agency,'' without thereby becoming substantive rules (*James A. Hurson Assocs.* v. *Glickman,* 229 F.3d 277, 280 (D.C. Cir. 2000)). If researchers want to increase the likelihood that their studies receive greater consideration by the EPA, they may take steps to ensure that the underlying dose-response data are available to the greatest extent possible. But any such response to this final rule would be purely voluntary. It is not required by this rule.

Some commenters also argued that this rule is not procedural because they asserted it conflicts with the substantive environmental statutes administered by the EPA. However, this final rule does not interpret or apply the provisions of any environmental statutes; such efforts will occur in the subsequent actions under the relevant statutes described above. As this rule makes clear, if implementing this procedural rule would result in conflicts with existing environmental statutes, and their implementing regulations, this rule will yield to the EPA statutes and regulations.

This is a rulemaking of agency organization, procedure, or practice. This procedural rule would not regulate any person or entity outside the EPA and would not affect the rights or obligations of outside parties. As a rule of Agency procedure, this rule is exempt from the notice-and-comment and delayed effective-date requirements set forth in the Administrative Procedure Act. See 5 U.S.C. 553(a)(2), (b)(A), (d). Nonetheless, the Agency voluntarily sought public comment on the proposed rule because it believed that the information and opinions supplied by the public would inform the Agency's views. *Vt. Yankee Nuclear Power Corp.* v. *Nat. Res. Def. Council, Inc.,* 435 U.S. 519, 524 (1978) (''Agencies are free to grant additional procedural rights in the exercise of their discretion.'') In addition, even assuming arguendo that the delayed effective-date requirement of the Act applied to this action, the EPA has determined that there would be good cause, consistent with 5 U.S.C. 553(d)(3), for making this final rule effective immediately because immediate implementation of the rule, with its goals of ensuring transparency and consistency in how the agency considers dose-response data underlying pivotal science to be used in significant regulatory decisions and influential scientific information, is crucial for ensuring confidence in EPA decision-making. Because this is a procedural rule that only applies internally to ensure that the EPA consistently considers data availability, the rationale for delayed effectiveness to allow reasonable time for non-EPA regulated entities to adjust their behavior before and prepare for the effective date of the new requirements does not apply. See *Omnipoint Corp.* v. *Fed. Commc'n Comm'n,* 78 F.3d 620, 630 (D.C. Cir. 1996); see also *United States* v. *Gavrilovic,* 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). For these reasons, the Agency

[5] *Chrysler Corp.,* 441 U.S. 281 at 301–02.
[6] *Id.* at 301 (quoting 5 U.S.C. 553(b), (d)).
[7] *Id.* at 302.

finds that good cause exists under APA section 553(d)(3) to make this rule effective immediately upon publication.

II. Background

A. Summary of 2018 Proposed Rule

In the 2018 proposed rule (Ref. 5), the EPA proposed adding 40 CFR part 30, which would direct the EPA to ensure that the pivotal regulatory science underlying its actions is publicly available in a manner sufficient for independent validation. The EPA proposed to take this action under the authority of the statutes it administers, including provisions providing general authority to promulgate regulations necessary to carry out the Agency's functions under these statutes and provisions specifically addressing the Agency's conduct of and reliance on scientific activity to inform those functions.

In the 2018 proposed rule, the EPA defined ''dose-response data and models,'' ''pivotal regulatory science,'' ''regulatory decisions,'' ''regulatory science,'' and ''research data'' (proposed 40 CFR 30.2).

Many of the provisions in proposed 40 CFR part 30 applied to dose-response models and data, regardless of the source of funding or identity of the party who developed the model or generated the data. Specifically, the EPA proposed that the Agency would ensure that dose-response data and models underlying pivotal regulatory science were publicly available in a manner sufficient for independent validation, including releasing information necessary for the public to ''understand, assess, and replicate findings'' (proposed 40 CFR 30.5). The public release of such information would be consistent with law; protect privacy, confidentiality, and confidential business information (CBI); and be sensitive to national security interests.

In addition to proposing requirements for ensuring that dose-response data and models were publicly available in a manner sufficient for independent validation, the EPA proposed additional requirements pertaining to the use of dose-response data and models underlying pivotal regulatory science. Proposed 40 CFR 30.6 would have required the EPA to: Describe and document any assumptions and methods used; clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions; evaluate the appropriateness of using default assumptions (*e.g.,* assumptions of a linear, no-threshold dose-response) on a case-by-case basis; and when available, give explicit consideration to high-quality studies that explore: A broad class of parametric dose-response or concentration-response models, a robust set of potential confounding variables, nonparametric models that incorporate fewer assumptions, the use of various threshold models across the dose or exposure range, and models that investigate factors that might account for spatial heterogeneity.

The 2018 proposed rule also included requirements that pertained more broadly to the use of studies in Agency actions and pivotal regulatory science. Proposed 40 CFR 30.4 would have required the EPA to clearly identify all studies relied upon when taking any final Agency action and make all such studies available to the public to the extent practicable. Proposed 40 CFR 30.7 would have required the EPA to conduct independent peer review of all pivotal regulatory science used to justify regulatory decisions. As part of the peer review, the EPA would have been required to ask peer reviewers to articulate the strengths and weaknesses of the Agency's justification for the assumptions applied and the implications of those assumptions for the results.

Finally, the 2018 proposed rule would have allowed for the EPA Administrator to grant exemptions to the requirements of the rule when the Administrator determined that compliance would be impracticable because it was not feasible to either (1) ensure that all dose-response data and models underlying pivotal regulatory science were publicly available in a manner sufficient for independent validation, in a fashion consistent with law; protective of privacy, confidentiality, and CBI; and sensitive to national security interests; or (2) conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in Section IX of the OMB Bulletin for Peer Review (Ref. 8).

The EPA solicited comment on the 2018 proposed rule generally and on specific provisions in the proposal, including the legal authority for the proposed rule, the scope of the proposal, public access to dose-response data and models, and how the proposed rule should be implemented.

B. Summary of 2020 Supplemental Notice of Proposed Rulemaking

The 2020 SNPRM (Ref. 7) included clarifications, modifications, and additions to certain provisions in the 2018 proposed rule. The 2020 SNPRM also revised the authority cited in proposed 40 CFR part 30; revised proposed 40 CFR 30.2, 30.3, 30.5, 30.6, 30.7, and 30.9; and deleted proposed 40 CFR 30.10.

Through the 2020 SNPRM, the EPA modified proposed 40 CFR part 30 to expand the scope of the 2018 proposed rule, clarified the intent of the 2018 proposed rule, and solicited public comment on two proposed approaches for how the Agency would consider data and model availability when evaluating studies. The 2020 SNPRM modified the scope of the 2018 proposed rule in two ways: (1) Expanded ''dose-response data and models'' to ''data and models,'' and (2) expanded the applicability of the proposed requirements to influential scientific information, which was defined in the 2020 SNPRM as the ''scientific information the Agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions,'' consistent with the definition of ''influential scientific information'' provided in the OMB Final Information Quality Bulletin for Peer Review (Ref. 8). As a result of the 2020 SNPRM, the provisions in proposed 40 CFR part 30 would have applied to data and models, regardless of the source of funding or identity of the party who developed the model or generated the data, underlying pivotal science or pivotal regulatory science. The EPA modified proposed 40 CFR 30.2, 30.3, 30.6, and 30.9 to reflect this change in scope of the proposed rulemaking.

With the expanded scope, the EPA proposed that data and models underlying pivotal regulatory science and pivotal science be available in a manner sufficient for independent validation. To clarify its intent, in the 2020 SNPRM the EPA modified and added proposed definitions for key terminology, including ''data,'' ''model,'' ''publicly available,'' and ''independent validation.'' Specifically, the EPA clarified that ''independent validation'' of data and models, as proposed, meant the ''reanalysis of study data by subject matter experts who have not contributed to the development of the study to demonstrate that the same analytic results reported in the study are capable of being substantially reproduced'' (2020 SNPRM proposed 40 CFR 30.2). In the 2020 SNPRM, the EPA also proposed definitions for ''reanalyze'' and ''capable of being substantially reproduced'' to further clarify the intent of the rulemaking.

In proposed 40 CFR 30.5, the EPA solicited public comment on two approaches for how the Agency would consider data and model availability

when evaluating studies underlying pivotal regulatory science and pivotal science. Under the first approach, the Agency would have only used pivotal regulatory science or pivotal science where the underlying data and models were either publicly available for independent validation or, in the case of restricted data and models (*e.g.,* those that include CBI, proprietary data, or personally identifiable information (PII) that cannot be sufficiently de-identified to protect the data subjects), available through restricted access in a manner sufficient for independent validation. Under the second approach, the EPA would have, other things equal, given greater consideration to studies where the underlying data and models were either publicly available in a manner sufficient for independent validation or, in the case of restricted data and models, available through restricted access in a manner sufficient for independent validation. Proposed 40 CFR 30.9 would have allowed the EPA Administrator to grant an exemption to the requirements in proposed 40 CFR part 30 if the Administrator determined that compliance was impracticable because technological barriers rendered sharing of the data or models infeasible; the development of the data or model was completed or updated before the effective date of this final rule; or by making the data and models publicly available, it would have conflicted with laws governing privacy, confidentiality, CBI, or national security interests.

Finally, the EPA clarified in the 2020 SNPRM that it is authorized to promulgate this rulemaking under its housekeeping authority and revised the authority cited in proposed 40 CFR part 30 accordingly. The Agency solicited public comment on whether to use its housekeeping authority independently or in conjunction with the environmental statutory provisions cited as authority in the 2018 proposed rule, which were further clarified in the 2020 SNPRM.

III. Description of Final Rule and Responses to Significant Comments

A. Purpose and Effect of the Action

1. *Purpose.* The EPA is committed to its mission of protecting human health and the environment through sound policy decisions that are informed by robust scientific and technical research. Because of the potential impact of the EPA's significant regulatory actions and influential scientific information on American lives and livelihoods, the American people deserve environmental decisions and policies that are based on the best scientific information. Only through continuous improvement to its procedures, especially those focused on transparency, can the EPA fully demonstrate that commitment.

The purpose of this action is to increase transparency by codifying internal procedural requirements for how the EPA will consider the availability of the underlying dose-response data that it relies upon to promulgate significant regulatory actions and develop influential scientific information. These requirements build upon open data initiatives in the Federal Government and scientific community and advance the EPA's mission and commitment to the public by prioritizing transparency of the underlying dose-response data in pivotal science for the most impactful of EPA's assessments and regulatory actions. Where underlying dose-response data in pivotal science are available, subject matter experts could independently reanalyze the data to affirm original research conclusions, check for errors, test alternative assumptions, and better understand and evaluate the implications of the uncertainty used in the original analysis. Such independent reanalyses will subsequently enable the EPA to make stronger, data-driven decisions in future rulemakings or in revisions to existing rules or influential scientific information. This could occur through standard cyclical reviews (*e.g.,* revisions to national ambient air quality standards, risk and technology reviews, national primary drinking water regulations), ad hoc revisions, or revisions through the information quality guidelines or other petition processes. Implementation of this rule will more effectively share pivotal science for external consideration and increase the opportunity for independent validation of pivotal science by subject matter experts. As data are better understood through independent reanalysis, the public will, if they so choose, be able to more effectively comment, engage, and hold the EPA accountable during the development of future significant regulatory actions and influential scientific information.

The transparency provisions in this final rule are intended to build upon existing Federal Government efforts and provide incremental progress toward the Agency's goal of greater transparency. The EPA and the Federal Government have long encouraged open data initiatives, as the principle of transparency in regulatory decision-making and the other operations of government agencies is a fundamental behavior of good government that is inherently valuable to the public. For example, in 2002 the Office of Management and Budget (OMB) released its *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies,* which includes discussion of the importance of the reproducibility of analyses underlying influential information (Ref. 3). The EPA's 2016 *Plan to Increase Access to Results of EPA-Funded Scientific Research* noted that ''transparency is a core EPA value'' and that increased availability of research data would accelerate scientific breakthroughs that support the Agency's mission and policymaking efforts (Ref. 9). The EPA's *Open Government Plan 5.0* (Ref. 10) also details the EPA's progress in implementing the tenets of the numerous data transparency initiatives in the Federal Government prior to 2018, including the Office of Management and Budget (OMB) M–10–06 (Ref. 11), the Office of Science and Technology Policy Memorandum of February 22, 2013 (Ref. 12), and OMB M–13–13 (Ref. 4). In 2019, Congress passed the Foundations for Evidence-Based Policymaking Act of 2018 (or OPEN Government Data Act, Public Law 115–435) into law, which included requirements for Federal agencies to prioritize making their data available to the public, and OMB has released additional guidance for implementing the act (Refs. 13, 14).

The scientific community has also embraced greater data transparency, as evidenced by data sharing and availability requirements for many high-impact journals (Ref. 15) and the emergence of organizations, such as the Center for Open Science, and international initiatives like Findable, Accessible, Interoperable, and Reusable (FAIR) data principles; Facilitate Open Science Training in European Research (FOSTER); and Guidelines for Transparency and Openness Promotion (TOP) in Journal Policies and Practices that incentivize greater transparency in research (Refs. 16, 17).

The EPA supports these efforts and is pursuing an incremental approach to maximizing transparency in the science that it relies upon to ensure that implementation is done in a thoughtful and deliberate way that focuses on the EPA's most impactful actions, minimizes unintended consequences, and informs future transparency requirements. As further described in Section II.B of this preamble, the EPA is focusing on the underlying dose-response data for this rulemaking because of the influence these data have on particularly impactful decisions at

the Agency. Risk assessments and regulations that target emissions and risk reduction of one or more pollutants, contaminants, or substances are integral to the Agency's mission and the underlying dose-response data that inform the quantitative value used to evaluate and mitigate potential risk are critical to understanding the assessment or regulatory action. In addition, the data underlying the dose-response assessment are more distinct than the broad range of data informing an entire risk assessment. Therefore, the EPA is concentrating its current efforts to increase transparency on a well-defined step in the quantitative assessment of risk supporting specific Agency actions. This final rule provides an important step in furthering the progress already being made toward maximizing transparency and will provide important insight for developing future statute-specific requirements.

Most public commenters on the purpose of the 2018 proposed rule and the 2020 SNPRM supported the concept of greater transparency, but questioned the ''problem'' the EPA was trying to fix. Other commenters indicated that it was not clear how greater data availability would fix these perceived problems, given what they asserted were limited detail in the proposed rule. Some public commenters and members of the EPA's Science Advisory Board (SAB) also suggested that issues related to transparency are or may be fixed with existing guidance, mechanisms, and other requirements. Other commenters questioned the motivation for the rulemaking, asserting that the rulemaking was the result of political interests, rather than scientific need; that it was biased to benefit industry; or that it was a deliberate attempt to suppress human health and climate studies. Some commenters contended that there was little evidence of a widespread reanalysis issue in science or, in particular, studies that would inform environmental policy. Other commenters contended that the rulemaking was at odds with the Agency's mission and would result in decreased environmental and human health protections. Some commenters asserted that the rule would lead to increased litigation and limit the public's trust in the EPA. Other commenters contended that the rule was inconsistent with practices in other Federal agencies and may adversely impact other Federal and state agencies that rely on EPA assessments.

Commenters supporting the rulemaking generally asserted that the greater transparency provided in the proposal and SNPRM was necessary and important for developing sound and scientifically robust regulations. Some commenters stated that transparency is a principle of good government. Some commenters noted specific benefits to greater transparency, including more effective public scrutiny and scientific debate, less political rhetoric, and clearer, more efficient regulations. Some commenters provided specific examples of EPA regulations or risk assessments that have relied on incorrect data or would have been improved with greater transparency. Other commenters contended that greater transparency was consistent or complementary with research and publishing policies, Federal Government policies, and the scientific method, while other commenters asserted that the rule would be an important improvement to transparency at the EPA.

The EPA continues to believe that codifying internal procedures aimed at prioritizing transparency in significant regulatory actions and influential scientific information into regulation will improve the opportunity for the public to access the EPA's scientific analyses and resulting regulatory actions in a way that is beneficial to the scientific process, the Agency's mission, and the public's health and safety. This rule is designed to build upon OMB M–19–15 (Ref. 18), which highlights the need to characterize the sensitivity of an agency's conclusions to analytic assumptions, as well as other Federal guidance documents that require greater data transparency (Ref. 18). The EPA's attention to data transparency is also responsive to the broader interest in greater data and model transparency observed in the numerous transparency initiatives in the scientific community and Federal Government, as well as the criticism the EPA has received from members of the public, scientific community, and Congress on the transparency of the scientific basis for EPA's decisions in previous influential scientific information assessments and regulatory actions (Refs. 19, 20, 21, 22, 23). The EPA's continued progress toward maximizing transparency is vital to building and maintaining trust with the public and credibility in the Agency's decisions.

The EPA disagrees with the contention that this rule is politically motivated, as transparency assumes no political ideology, nor is this rule likely to result in decreased human health or environmental protections, as the benefits of greater data transparency and the significance of reanalyzing and validating study results are well-documented in scientific literature. McNutt (2014) noted, ''reproducibility, rigor, transparency, and independent verification are cornerstones of the scientific method'' (Ref. 24). The National Academies of Sciences, Engineering, and Medicine (NAS) workshop on Reproducibility and Replicability in Science also noted that ''certainly, reproducibility and replicability play an important role in achieving rigor and transparency'' (Ref. 16).[8] Munafò et al. (2017) state, ''the credibility of scientific claims is rooted in the evidence supporting them, which includes the methodology applied, the data acquired, and the process of methodology implementation, data analysis and outcome interpretation. Claims become credible by the community reviewing, critiquing, extending and reproducing the supporting evidence. However, without transparency, claims only achieve credibility based on trust in the confidence or authority of the originator. Transparency is superior to trust'' (Ref. 25). The 2019 NAS workshop on Reproducibility and Replicability in Science also concluded, ''the scientific enterprise depends on the ability of the scientific community to scrutinize scientific claims and to gain confidence over time in results and inferences that have stood up to repeated testing'' (Ref. 16). Importantly, the workshop also concluded that researchers, funding institutions, and journals could make advancements to improve reproducibility, rigor, and transparency (Ref. 16).

The EPA agrees that data transparency is vital for individuals who have not contributed to the study to be able to verify the quality and strength of published studies and agrees with commenters that the opportunity to independently validate the pivotal science that the EPA relies upon is important in furthering scientific understanding and the Agency's mission. A presenter in a 2016 NAS workshop on Principles and Obstacles for Sharing Data from Environmental Health Research stated more directly that ''for environmental policy making to be legitimate, the scientific reasoning behind a given decision—including the data supporting it—must be transparent'' (NAS Workshop Report, Ref. 26). When data are widely available, researchers can validate

[8] The NAS workshop on Reproducibility and Replicability in Science defines ''reproducibility'' to mean the extent to which a researcher can obtain consistent computational results using the same input data, computational steps, methods, code, and conditions of analysis. The use of ''reproducibility'' by the NAS is consistent with the intent of the use of ''independent validation'' in this rule.

research results and help identify and correct unintended errors, as well as reanalyze the data for new and different purposes, examine novel questions, provide new scientific insights, and improve model development. In its April 24, 2020, letter to EPA Administrator Wheeler (Ref. 27), the EPA's SAB noted that it

> ''recognizes the importance of this rule and its purpose, establishing transparency of the influential scientific information used for significant regulations and enhancing public access to scientific data and analytical methods to help ensure scientific integrity, consistency and robust analysis. Strengthening transparency by improving access to data can lead to an increase in the quantity and the quality of evidence that informs important regulatory and policy decisions. The scientific community is moving toward adopting the precept of sharing accurate data and information to increase credibility, high-quality outcomes and public confidence in science. The SAB supports the adoption of this precept.'' [9]

The EPA also agrees with commenters that the scientific community and government agencies are making great strides in data transparency; however, improvements can still be made over existing policies and mechanisms. Many scientific publications, for example, require authors to make a data availability or data access statement, which discloses where and under what conditions the underlying study data are available. Yet the EPA cannot solely rely on data availability statements made in published research because initiatives toward greater data sharing and transparency amongst scientific journals and international organizations are still being implemented, are inconsistently enforced, and the true accessibility of data in a public repository is still limited (Refs. 28, 29, 30, 31, 32, 33). For example, Christensen et al. (2019) evaluated 1,072 peer-reviewed articles and ''found that rates of data availability for empirical articles published after journals adopted data-sharing policies differ widely between journals, from 0 percent to 83 percent, with a mean of 35 percent'' (Ref. 32). Stodden et al. (2018) noted they were only able to retrieve the dataset and code for 44 percent of the 204 computational studies published in *Science* in the 16 months after the publisher instituted its data availability requirements (Ref. 34). Therefore, the rule requirements for the EPA's independent evaluation of the availability of data are necessary and critical to prioritizing data transparency in the pivotal science underlying its significant regulatory actions and influential scientific information.

Finally, focusing the final rule requirements on the underlying dose-response data is intended to address public comments concerning clarity of the rule, potential unintended consequences, and the potential for far-reaching impacts. The requirements provide a workable framework for evaluating pivotal science in the context of the availability of its underlying dose-response data, while balancing important technical considerations in order to ensure the Agency maintains a strong scientific basis for its decision-making. The incremental progress made possible by this rule provides an important step towards prioritizing transparency in particularly impactful EPA rules and assessments and will inform future statute-specific rulemakings.

2. Effect of this rule on the studies the EPA uses to support significant regulatory actions and influential scientific information. The EPA received significant comment on the effect of the 2018 proposed rule and 2020 SNPRM on the studies the Agency would be able to consider and use to support significant regulatory actions and influential scientific information. Many commenters asserted that the EPA's action, if finalized, would limit the scientific studies the EPA could use because the EPA would exclude from consideration any studies where the underlying data and models could not be made publicly available or available in a manner sufficient for independent validation.

As discussed in Section III.B of this preamble, based on a consideration of the public comments on the 2018 proposed rule and the 2020 SNPRM, the EPA is finalizing internal procedural requirements for how the Agency will consider the availability of underlying dose-response data of pivotal science when promulgating a significant regulatory action or developing influential scientific information that relies on dose-response data. The EPA is also further clarifying how the Agency will determine the consideration to afford to pivotal science in either significant regulatory actions or influential scientific information.

Consistent with existing Agency practice (Ref. 35), the EPA will review and evaluate all relevant scientific studies when developing significant regulatory actions and influential scientific information. The EPA will continue to use the following, established factors to assess the quality of studies used to develop significant regulatory actions and influential scientific information (Refs. 36, 37):

- Soundness—The extent to which the scientific and technical procedures, measures, methods or models employed to generate the information are reasonable for, and consistent with, the intended application.
- Applicability and Utility—The extent to which the information is relevant for the Agency's intended use.
- Clarity and Completeness—The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations and analyses employed to generate the information are documented.
- Uncertainty and Variability—The extent to which the variability and uncertainty (quantitative and qualitative) in the information or in the procedures, measures, methods or models are evaluated and characterized.
- Evaluation and Review—The extent of independent verification, validation and peer review of the information or of the procedures, measures, methods or models.

When evaluating potential links between exposure to a pollutant, contaminant, or substance and effects and the nature of the dose-response relationship, the EPA will follow best practices and rely on the highest quality, most relevant studies in determining the potential for hazard due to exposure to a pollutant, contaminant, or substance. Where there is convincing and well-substantiated evidence (consistent with Agency guidelines on hazard identification and dose-response assessment) to support a relationship between exposure and effect, the EPA will identify a subset of those studies for use in characterizing the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect. This will be based on the exposure situation being addressed, the quality of the studies, the reporting adequacy, and the relevance of the endpoints. From that subset, the specific dose-response studies or analyses that drive the requirements, quantitative analyses, or both will be identified as pivotal science (see Section III.E of this preamble).

Once the EPA has identified pivotal science—for either significant regulatory actions or influential scientific information—the EPA will then evaluate if the underlying dose-response data are available in a manner sufficient for independent validation. The EPA will give greater consideration to pivotal science for which the underlying dose-response data are either publicly available in a manner sufficient for

[9] The SAB also provided several constructive comments and recommendations, which have been considered in the development of this final rule.

independent validation or, in the case of PII, CBI, or proprietary data, available through restricted access that affords privacy in a manner sufficient for independent validation.

The EPA acknowledges, and agrees with commenters, that there may be pivotal science for which the underlying dose-response data are not publicly available due to technological feasibility or cannot be made available in a secure environment that still allows for independent analysis. For example, dose-response data underlying older pivotal science may no longer be available or may not exist in a currently usable format. In these cases, the EPA may still use the pivotal science after either giving it lesser consideration or receiving an exemption from the requirements of this rule from the Administrator (see Section III.G of this preamble). See Section III.E of this preamble for a description of the factors the EPA will consider when determining the consideration to afford to pivotal science when the underlying dose-response data are not available for independent validation.

The EPA expects to identify pivotal science, and the consideration afforded to pivotal science, in proposed significant regulatory actions and external review drafts of influential scientific information, which will allow the subject matter experts, if they so choose, to independently validate the pivotal science and provide comment to the EPA. The EPA believes that this approach will allow the public to more effectively comment, engage, and hold the EPA accountable during the future development of specific significant regulatory actions and influential scientific information.

3. Effect of this rule on human health and environmental protection. Many commenters contended that the 2018 proposed rule and the 2020 SNPRM would prevent the EPA from meeting its statutory obligations and performing its mission of protecting human health and the environment. Some commenters asserted that, by excluding studies based on data availability, the EPA would develop regulatory decisions that are: (1) Not based on high-quality studies or the best available science; and (2) potentially biased towards regulated parties. As a result, these commenters argued that human health and environmental protections would decrease. Several commenters contended that decreased human health and environmental protections would disproportionately affect communities of color, indigenous communities, and low-income communities because these communities are more likely to live or work near sources of pollution.

The EPA considered these comments when finalizing this rule, and the EPA does not agree that its approach will lead to systematic bias towards certain types of stakeholder goals. As described above, the EPA is not categorically excluding any studies from consideration when promulgating significant regulatory actions or developing influential scientific information. Rather, the Agency will continue to evaluate the quality of all relevant studies, consistent with the intended use of the information. The EPA will also continue to rely on the highest quality, most relevant studies available in determining the potential for hazard due to exposure to a pollutant, contaminant, or substance.

When characterizing the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect, the EPA will identify pivotal science and give greater consideration to pivotal science for which the underlying dose-response data are available in a manner sufficient for independent validation. Including this review of dose-response data availability for pivotal science is critical to the EPA's progress toward increased transparency and providing increased opportunity for scientific reanalysis and review by independent third parties. This approach will result in significant regulatory actions and influential scientific information that are based on high quality studies that maximize transparency, leading to human health and environmental protections consistent with the statutes the EPA administers.

In response to the 2018 proposed rule, the EPA received comments on perceived conflicts between the requirements included in the 2018 proposed rule and statutory requirements that direct EPA to consider certain data and information when developing Agency actions. For example, some commenters contended that the requirements in the 2018 proposed rule conflicted with the FIFRA pesticide registration requirements and associated implementing regulations, which require registrants to submit data and information to the EPA to enable the Agency to make its unreasonable adverse effects determinations. These commenters argued that, under the 2018 proposed rule, the EPA would not be able to consider these data, which are often claimed as CBI, when evaluating the pesticide registrations because the data could not be made publicly available. In response to this comment and other similar comments, the EPA clarified in the 2020 SNPRM the relationship between this rulemaking, the environmental statutes and their implementing regulations by adding language to proposed 40 CFR 30.3 stating that statutory requirements and corresponding implementing regulations would control in the event of any conflicts.

With this final rule, the EPA is maintaining language from the 2020 SNPRM in 40 CFR 30.3 stating that statutory requirements and corresponding implementing regulations will control in the event of any conflict, and clarifying in this preamble that the requirements in this final rule set the overarching structure and principles for transparency in significant regulatory actions and influential scientific information. The EPA plans to promulgate either statute-specific transparency regulations or programmatic actions implementing this procedural rule, as appropriate, to clarify how the Agency will implement the provisions from this final rule for specific programs authorized under the statutes the EPA administers.

B. Dose-Response Data

The 2018 proposed rule focused on dose-response data and models, although not consistently. For example, some parts of the proposed regulatory text appear to limit applicability of certain provisions to only dose-response models. In others, the proposed requirements would apply more broadly. Commenters noted this variability. As a result, in the 2020 SNPRM, the EPA proposed a consistent, broader applicability to data and models.

The EPA received significant comment on this proposed expansion of the applicability of the rulemaking to data and models. While some commenters supported this expansion, other commenters contended that the applicability to dose-response data and models was already very broad, and that the broader applicability would significantly limit the information that the EPA could consider in a broad ranges of assessments (*e.g.,* bioaccumulation data, data on environmental releases, exposure estimates used by the EPA across the environmental statutes that it administers). Some commenters contended that the EPA did not provide sufficient rationale to support this expansion.

Based on the comments on the 2018 proposed rule and the 2020 SNPRM, taking into account the number of studies that would be subject to the rule, the EPA determined that the Agency

should pursue an incremental approach to maximizing transparency in the science that it relies upon by focusing the final rule requirements on dose-response data and, in particular, only those studies that are integral to characterizing dose-response relationships (*e.g.,* identifying candidate PODs). The EPA considered commenters' assertions that the scope of the 2018 proposed rule would be so broad as to make implementation infeasible. The 2018 proposed definition of ''dose-response data and models'' would apply to dose-response data [and models] ''used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a predicted health or environmental impact.'' This relationship of the dose-response data to the magnitude of a predicted health or environmental impact would require the consideration of an array of studies beyond those that characterize dose-response relationships, including, for example, studies that inform the dose-response modeling (*e.g.,* benchmark response selection); studies that identify data for toxicokinetic adjustments that inform calculation of a human-equivalent point of departure (POD); and studies that inform the selection of uncertainty factors. The number of studies that are used to establish the relationship between dose-response data and models and the magnitude of a predicted health or environmental impact can potentially be very large. This may make implementing the rule, as proposed, more challenging for at least some significant regulatory actions and influential scientific information. While transparency in EPA decision-making is the purpose of this action, the EPA prefers an incremental approach. Rather than having this final rule apply to all the studies that support the assessment of the relationship of a dose or exposure of a pollutant, contaminant, or substance to the magnitude of a predicted health or environmental impact, the EPA is balancing transparency and feasibility by focusing on those studies that describe the quantitative relationship between the dose or exposure of a pollutant, contaminant, or substance and an effect. Specifically, the scope of dose-response data in this final rule is those studies consisting of the data integral to characterizing dose-response relationships. In some instances, this group will consist of a handful of studies. In other instances, where there are multiple toxicity endpoints, there may be more studies that are crucial to characterizing dose-response relationships. In some other cases, there may be a large number of studies that are used to characterize a dose-response relationship (*e.g.,* where the dose-response is based on a meta-regression of epidemiology studies). However, not all of these studies would be considered pivotal science (see Section III.C.6 of this preamble for the definition of ''pivotal science'').

Based on comments and other considerations, the EPA is concentrating its efforts in the final rule to increase transparency on dose-response data, as the dose-response data are discrete and the dose-response assessment is a well-defined and impactful step in the quantitative assessment of risk. This final rule provides an important step in furthering progress toward maximizing transparency and will provide insight for future statute-specific requirements. Consistent with this targeted focus, the EPA is replacing the proposed definition of ''dose-response data and models'' at 40 CFR 30.2 with a definition of ''dose-response data'' (see Section III.C of this preamble).

C. Definitions

The 2018 proposed rule included proposed definitions for ''dose-response data and models,'' ''pivotal regulatory science,'' ''regulatory decisions,'' ''regulatory science,'' and ''research data.'' Some commenters stated that several of the proposed definitions were unclear, including some that seemed to overlap (*e.g.,* ''pivotal regulatory science'' and ''regulatory science''). Some commenters also stated that certain terms used in the proposed regulatory requirements were not clear and should be defined.

In response to these comments on the 2018 proposed rule, the EPA proposed in the 2020 SNPRM definitions for ''capable of being substantially reproduced,'' ''data,'' ''independent evaluation,'' ''models,'' ''publicly available,'' and ''reanalyze.'' In the 2020 SNPRM, the EPA also proposed a definition of ''influential scientific information'' to comport with the proposed expansion of the applicability of the rulemaking to influential scientific information.

Based on a consideration of the public comments on both the 2018 proposed rule and the 2020 SNPRM, the EPA is finalizing the definitions at 40 CFR 30.2 as follows.

1. *Capable of being substantially reproduced, independent validation, and reanalyze.* In the 2018 proposed rule, the EPA used the term ''replicate'' in the proposed regulatory text at 40 CFR 30.5 but did not define it at 40 CFR 30.2. Proposed 40 CFR 30.5 read, in pertinent part, ''[i]nformation is considered 'publicly available in a manner sufficient for independent validation' when it includes the information necessary for the public to understand, assess, and replicate findings . . . .'' Some commenters contended that the EPA was not clear about what it meant by the term ''replicate'' and interpreted the term ''replicate'' in several different ways. For example, some commenters asserted that the EPA used the term ''replicate'' but actually meant ''reanalyze.'' The EPA finds that these comments have merit and is clarifying that the intent of the term in the proposed regulatory text at 40 CFR 30.5 was ''reanalyze'' rather than ''replicate.'' In the 2020 SNPRM, the EPA proposed using the term ''reanalyze'' instead of ''replicate'' and proposed at 40 CFR 30.2 a definition for ''reanalyze.'' Given that proposed 40 CFR 30.5 also included the term ''independent validation'' and that this term directly relates to ''replicate,'' the EPA also proposed a definition at 40 CFR 30.2 for this term. The proposed definition of ''independent validation'' included the term ''capable of being substantially reproduced.'' The EPA also defined this term because it was an important component of the definition of ''independent validation.''

While commenters generally supported the inclusion of the proposed definitions for ''capable of being substantially reproduced,'' ''independent validation,'' and ''reanalyze,'' some commenters addressed aspects of the proposed definitions and suggested modifications. One commenter suggested replacing the term ''validation'' with ''verification'' because they asserted the term ''validation'' has specific meanings in the context of assay development and in the context of model development. The EPA understands that the term validation is used differently in some scientific disciplines than the EPA has defined it. However, for the purposes of this rule, the EPA has defined validation in terms of independent reanalysis.

Another commenter contended that the proposed definition of ''independent validation'' was inconsistent with the remainder of the proposal because it restricts the concept of ''independent validation'' to ''subject matter experts who have not contributed to the development of the study,'' rather than the public as was the stated intent of the rule. Because this rule is about scientific data, the EPA finds it unlikely that without the necessary expertise, one could reasonably reanalyze the dose-response data underlying pivotal

science. This final rule does not preclude the public from engaging subject matter experts to determine whether a study can be independently validated. Also, the definition cannot be considered solely in isolation. The regulatory text in which the term is used informs the extent of the availability of dose-response data underlying studies. Specifically, 40 CFR 30.5 requires, in part, that the dose-response data underlying studies that the EPA will consider as pivotal science be available in a manner sufficient for independent validation. Scientific information is considered available in a manner sufficient for independent validation when it includes the information necessary to understand, assess, and reanalyze findings. The efficacy of the reanalysis will depend on the expertise of the person conducting the reanalysis.

One commenter noted that the term ''reproduced'' in the proposed definition of ''capable of being substantially reproduced'' and the use of ''capable of being substantially reproduced'' in the proposed definition of ''independent validation,'' were inconsistent with the description of reproduce in the 2020 SNPRM preamble and the NAS Workshop Report (Ref. 26). The commenter contended that this adds confusion. Another commenter asserted that there is insufficient guidance or standards for what the term ''substantially'' means or who will make the determination (*e.g.,* scientific staff with oversight of an EPA scientific advisory panel). Another commenter stated that there were inconsistencies with the proposed definitions for the terms ''capable of being substantially reproduced'' and ''reanalyze.'' Commenters asserted that the former proposed definition specifies the use of ''identical methods,'' whereas the latter proposed definition specifies the use of the ''same or different'' methods.

The EPA finds that these comments have merit. The EPA is modifying the definition of ''independent validation'' in the final rule by replacing ''capable of being substantially reproduced'' with ''produced.'' The EPA will not finalize the proposed 40 CFR 30.2 definition of ''capable of being substantially reproduced'' because the term is not used in the final rule's definition of ''independent validation'' or elsewhere in 40 CFR 30. As a result, ''substantially'' will not need to be defined or described in the final rule. The EPA is also modifying the definition of ''reanalyze'' to specify the use of the same methods because as proposed it specified the use of the ''same or different'' methods. This change was made so that the definition would be consistent with the final rule's definition of ''independent validation.''

2. *Data and models.* In the 2020 SNPRM, the EPA proposed a definition of ''data'' in response to comments on the 2018 proposed rule, contending that a definition for this term was needed to clarify the applicability of the rulemaking. Commenters requested that the EPA clarify which stage of data would need to be available to allow for independent validation. The stage of data that the EPA identified in the proposed 40 CFR 30.2 definition of ''data'' is based on the discussion of the different stages of data in the NAS Workshop Report (Ref. 26). The 2020 SNPRM adapted the description of the stage of data from the NAS Workshop Report (Ref. 26) that was data at the appropriate level of detail to allow for independent validation via reanalysis.

Several commenters asserted that the proposed definition of ''data'' was so broad that it could include potentially any information. One commenter contended that as published scientific results are often the final steps in a process involving several processing and analysis steps, the proposed definition of ''data'' definition did not identify what intermediate step of data processing would be subject to this rule. The commenter noted that determining which of the multiple data processing and analysis steps that should be used would differ from study to study. Another commenter suggested that the EPA should identify the actual final dataset used in statistical analysis as the appropriate stage of data to be made available.

As the EPA described in the 2020 SNPRM, there are different stages of data. The EPA presented the different stages described in the NAS Workshop Report (Ref. 26), ''There are raw data, which come straight from the survey or the experiment. There are cleaned-up data, which consist of the raw data modified to remove obvious errors.'' (These are the data that are ready to be analyzed to extract relevant information.) ''There are processed data, which are data that have been computed and analyzed to extract relevant information. There is the final clean data set that is provided with a publication.'' Since the purpose of 40 CFR 30.5 is to determine the consideration to afford to studies based on, among other factors, the availability of the underlying dose-response data that would support independent validation via reanalysis of the data underlying pivotal science, the appropriate stage of data would not be the processed data (data that have been computed and analyzed to extract relevant information) or the final clean data set that is provided with a publication. At these two stages of data, the analysis has already been conducted, and the results have already been determined. In order to determine if these results are valid, data that had not already been computed and analyzed are needed.

In this final rule, the EPA is not identifying a specific step in a multi-step analysis as the stage of data that would be sufficient for independent validation through reanalysis because this would be overly prescriptive and not informative. As noted by commenters, the step at which the final clean data set will be generated will vary from study to study. The level of detail required would be that needed for a separate party to reanalyze the study. The appropriate step is where the data are ready to be analyzed to extract relevant information.

One commenter requested that the EPA introduce and define a new term, ''validated data,'' which are the data with the proper level of quality assurance. While the EPA routinely conducts quality assurance to ensure that data are acceptable for use, the EPA does not see the need to create a separate definition. The focus of this rulemaking is the independent validation of the results of studies underlying pivotal science, not the quality assurance of the data itself.

Some commenters contended that the EPA should define ''data'' as the raw data in which obvious errors have not been removed. Other commenters stated that raw data in which obvious errors have not been removed would result in skewed analyses for third parties not familiar with the data collection process. Given concerns about potentially skewed analyses, the final definition of ''data'' maintains the stage of data in which obvious errors have been removed.

Some commenters also requested that the EPA define ''model'' to clarify the applicability of the rulemaking. In the 2020 SNPRM, the EPA proposed a definition of ''model'' at 40 CFR 30.2, but the Agency is not finalizing the definition of ''model'' because this regulation applies only to dose-response data (see Section III.B of this preamble).

3. *Dose-response data.* In the 2018 proposed rule, the EPA proposed a definition of ''dose-response data and models.'' The EPA did not receive significant comment on the definition of ''dose-response data and models'' itself. However, as discussed in Section III.B of this preamble, this final rule applies to dose-response data, and thus the EPA is not finalizing a definition for ''dose-

response data and models.'' Rather, consistent with the applicability of this final rule, the EPA is finalizing a definition of ''dose-response data'' that is specific to the relationship between a dose or exposure and an effect.

4. *Influential scientific information.* In the 2020 SNPRM, the EPA proposed expanding the scope of the 2018 proposed rule to include influential scientific information and proposed to define ''influential scientific information'' as ''scientific information the Agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions,'' consistent with the definition of ''influential scientific information'' provided in the OMB Final Information Quality Bulletin for Peer Review (Ref. 8).

The EPA received public comments in support of and against the Agency's proposed 40 CFR 30.2 definition of ''influential scientific information.'' Some commenters believed that the proposed definition was too broad to be useful and, as a result, would apply to all scientific documents produced by the EPA. Other commenters believed that the proposed definition was too narrow and would not adequately capture the types of information that may be considered influential.

The EPA finds that these comments have merit, in part. The definition of ''influential scientific information'' at proposed 40 CFR 30.2 in the 2020 SNPRM is the same definition as in the OMB Final Information Quality Bulletin for Peer Review (Ref. 8). The EPA proposed to adopt this definition because it intended the scope to be consistent with how that term has been interpreted and applied in the context of peer review.[10] Given that the definition is both established and has been routinely applied by the EPA, the EPA disagrees with the suggestion that the term is inherently too narrow or too broad. Rather than modify the proposed 40 CFR 30.2 definition of ''influential scientific information,'' the EPA is modifying 40 CFR 30.3 in the final rule to clarify the Agency's intent that the requirements in 40 CFR 30.3 apply to influential scientific information, unless the influential scientific information is exempted from peer review requirements as described in Section IX of the OMB Final Information Quality Bulletin for Peer Review (Ref. 8). Consistent with this approach, the EPA is finalizing the definition of ''influential scientific information'' as proposed in the 2020 SNPRM.

5. *Pivotal science.* In the 2020 SNPRM, the EPA introduced the term ''pivotal science,'' defined in proposed 40 CFR 30.2 as ''the specific scientific studies or analyses that underly [sic] influential scientific information.'' This term was proposed as a parallel to ''pivotal regulatory science,'' defined in 40 CFR 30.2 of the 2018 proposed rule as ''the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA significant regulatory decisions.''

The EPA received comment on the use of ''regulatory'' in ''pivotal regulatory science.'' Some commenters contended that there is no such thing as science that is regulatory; rather, there is science used to support regulation. Some commenters also noted that the terms ''pivotal science'' and ''pivotal regulatory science'' have similar scopes.

The EPA acknowledges that no scientific study is inherently regulatory; rather, the EPA uses science to inform its significant regulatory actions. In order to increase the clarity of this final rule, to take into account the similarities between the two definitions, and to more accurately describe the science that the EPA uses, the EPA is removing the term ''pivotal regulatory science'' and combining the definitions of ''pivotal science'' and ''pivotal regulatory science'' under the single term ''pivotal science'' in 40 CFR 30.2. The EPA is responding to comments on both terms together.

Some commenters noted that the scope of studies that could be considered ''pivotal science'' was unclear but appeared broad. Some commenters argued that since properly conducted science reviews the entire body of scientific evidence, nearly any study evaluated could be considered ''pivotal science.'' The EPA's SAB suggested that the Agency clarify whether ''pivotal science'' refers to all the hazard characterization and dose-response models that the EPA evaluates and captures in its analysis (Ref. 27). Other commenters asserted that if the EPA interprets ''pivotal science'' broadly to include all studies involved in the development of significant regulatory actions or influential scientific information, implementing this rule would be infeasible.

As discussed in Section III.B of this preamble, the EPA finds merit in comments that the proposed definition for ''pivotal science'' appeared too broad to feasibly implement in this rule. Because of the EPA's commitment to basing its decisions on sound science, the EPA may review several hundred or thousands of scientific studies in the development of significant regulatory actions or influential scientific information. As such, the EPA agrees that determining data availability for all the studies EPA considers in significant regulatory actions and influential scientific information may be infeasible at this time. Future statute-specific rulemakings may be more expansive as the EPA continues to make incremental progress toward maximizing transparency.

Further, although this rulemaking does not require reanalysis of a study's underlying data, the EPA finds that limiting the scope of ''pivotal science'' will still provide meaningful and impactful opportunity for reanalysis. Lewandowsky et al. (2020) evaluated the cost-effectiveness of reanalysis studies under various scenarios and concluded that reanalysis studies are most cost-effective when they are focused on studies of the greatest interest to the scientific community (in this study, the number of citations was a surrogate for interest) (Ref. 38). This finding is consistent with results in other studies that found and encouraged narrowing the focus of attempted reanalysis studies to those studies of greater significance (Refs. 37, 39, 40, 41).

In this final rule, rather than considering all studies that support the assessment of the relationship of a dose or exposure of a pollutant, contaminant, or substance to the magnitude of a predicted health or environmental impact as ''pivotal science,'' the EPA is balancing transparency and feasibility by focusing on those studies that inform the quantitative relationship between the dose or exposure of a pollutant, contaminant, or substance and an effect. Thus, ''pivotal science'' includes only those studies that are integral to characterizing dose-response relationships (*e.g.,* identifying candidate PODs). These are the studies that drive the requirements or quantitative analyses of EPA significant regulatory actions or influential scientific information. Although this rule takes an incremental approach and therefore does not include studies informing the dose-response modeling (*e.g.,* benchmark response selection), studies identifying data for toxicokinetic adjustments, or studies informing the selection of uncertainty factors do not drive the requirements or quantitative analyses of EPA significant regulatory actions or influential scientific

[10] For example, see the Environmental Protection Agency Annual Report on Peer Review Fiscal Year 2017 (October 1, 2016–September 30, 2017) that the Agency submitted to OMB, *https://cfpub.epa.gov/si/EPA%20FY%202017%20Annual%20Peer%20Review%20Report.pdf.* Each annual report identifies influential scientific information and highly influential scientific assessments.

information. Future statute-specific rulemakings may interpret ''pivotal science'' more broadly.

This clarified definition of ''pivotal science'' in the final rule is also responsive to the SAB's comments that pivotal science should be more focused (Ref. 27). Consistent with the intent of this rulemaking, the EPA intends to clearly identify the studies considered pivotal in the documentation at the proposed rule stage for significant regulatory actions and when influential scientific information is disseminated for peer review.

Some commenters also expressed confusion regarding how ''pivotal science'' relates to ''best available science.'' One commenter recommended that if this rulemaking is intended to alter the EPA's definition and use of the best available science, the EPA should issue further guidance for public comment. To be clear, this rulemaking is not intended to modify the Agency's interpretations of ''best available science.'' The EPA will continue to consider all peer-reviewed science, consistent with existing study quality assessment factors and corresponding statutory mandates. The EPA will then identify and consider ''pivotal science in accordance with the provisions of this rule,'' unless the implementation of the rule conflicts with statutory requirements and associated implementing regulations.

6. *Publicly available.* In the 2018 proposed rule, the EPA used the term ''publicly available,'' but did not propose a definition at 40 CFR 30.2 or describe it in the preamble to the 2018 proposed rule. Some commenters on the 2018 proposed rule asked the EPA to explain what it meant by the term. In the 2020 SNPRM, the EPA proposed a definition for ''publicly available'' at 40 CFR 30.2.

One commenter stated that the proposed definition was vague because it did not make clear whether the study data itself would proactively be made available to members of the public by data holders in government sources, media sources, or other online sources. The definition is not intended to describe the mechanism for making the information available (*i.e.,* whether the information is made available proactively or is made available upon request). Rather, the definition describes whether, given the nature of the information, it can be, must be, or is already generally available (*i.e.,* where the information can be made lawfully available from government records, is required to be made available by government law or regulation, or is information that is widely available to the general public).

Another commenter requested that the EPA consider data and models to be publicly available when they are available through restricted access when the data includes CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects. The EPA disagrees with the commenter. The plain meaning of ''publicly available'' does not include availability through restricted access to data that includes CBI or PII because there are laws that preclude the disclosure of CBI or PII to those not authorized for its access. Thus, the general public cannot access the un-sanitized CBI data or non-anonymized PII data in a manner that will allow for independent validation through reanalysis. If the public cannot access such data, it is not publicly available.

Several commenters contended that the proposed definition of ''publicly available'' would introduce a bias favoring industry data submitted to the EPA. They asserted that industry-generated studies submitted to the EPA pursuant to FIFRA would be considered publicly available because they could be obtained by the public in response to a Freedom of Information Act (FOIA) request. However, this does not mean that these are immediately or easily available to the public. Some commenters cited the EPA's *Freedom of Information Act Annual Report Fiscal Year 2019* (2020), which lists a median response time for ''expedited processing'' of FOIA requests by the EPA as 493 days (Ref. 42). The EPA finds that such comments have merit and is modifying the definition in the final rule to add the following at the end of the definition: '''''the public must be able to access the information on the date of publication of the proposed rule for the significant regulatory action or dissemination of the draft influential scientific information for public review and comment.''

7. *Research data.* Proposed 40 CFR 30.2 in the 2018 proposed rule included a definition of ''research data.'' In the 2020 SNPRM, the EPA deleted the proposed definition of ''research data.'' While one commenter on the 2020 SNPRM noted that the exclusions in the proposed definition of ''research data'' of trade secrets and personal and medical information were not incorporated into the proposed definition of ''data,'' commenters did not request that the EPA maintain a definition of ''research data.'' The EPA is not including a definition of ''research data'' in this final rule given that it is finalizing the definition of ''data.''

8. *Significant regulatory actions.* In the 2018 proposed rule, the EPA defined the term ''regulatory decisions'' as final regulations determined to be significant regulatory actions under Executive Order (E.O.) 12866, *Regulatory Planning and Review.* Some commenters stated that the use of regulatory decisions was confusing given that the term was only intended to apply to a subset of regulations. The EPA agrees with these comments, and to clarify the definition, the Agency is changing the term from ''regulatory decisions'' to ''significant regulatory actions'' in the final rule.

9. *Science that serves as the basis for informing a significant regulatory action.* In the 2018 proposed rule, the EPA proposed to define the term ''regulatory science.'' A number of commenters expressed confusion over both the meaning and scope of this proposed term. One commenter noted that other Federal agencies have defined ''regulatory science.'' For example, the U.S. Food and Drug Administration (FDA) has described ''regulatory science'' as ''the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products'' (Ref. 43).This commenter suggested that a simplified definition would be ''regulatory science consists of the scientific segment of the regulatory process.'' The EPA acknowledges that the term ''regulatory science'' may be confusing because it suggests either that the term refers to a scientific discipline of regulatory decision-making (akin to FDA's description), or that the EPA considers some science inherently regulatory. Neither of these interpretations reflects the Agency's intent in defining this term. The EPA considers the breadth of scientific evidence in its rulemakings; while this scientific evidence informs policy decisions, the EPA's consideration of the science does not make it ''regulatory science.'' To reflect this fact, in the final rule the EPA is changing the proposed term ''regulatory science'' to ''science that serves as the basis for informing a significant regulatory action.''

In the 2018 proposed rule, the EPA defined regulatory science as ''scientific information, including assessments, models, criteria documents, and regulatory impact analyses, that provide the basis for EPA final significant regulatory actions.'' Several commenters claimed that this definition was vague and without discernable meaning. The EPA disagrees with the assertion that the proposed definition was without meaning, but in response to comments

is altering the final definition to increase clarity. For example, the EPA notes that the proposed definition for ''regulatory science'' combined both general categories of scientific information, such as assessments and models, with specific examples of EPA scientific products, such as criteria documents and regulatory impact analyses. The EPA acknowledges that this may increase confusion and is therefore limiting the final definition to general categories. As such, the EPA is altering the definition of ''science that serves as the basis for informing a significant regulatory action'' in 40 CFR 30.2 to mean ''studies, analyses, models, and assessments of a body of evidence that provide the basis for EPA significant regulatory actions.'' Examples of models include those used in regulatory impact analyses. Examples of assessments of a body of evidence include risk assessments, hazard identifications, Integrated Risk Information System (IRIS) assessments, and criteria documents.

Other commenters expressed confusion over the scope of what constitutes science that serves as the basis for informing a final significant regulatory action, as defined in the proposed rule. One commenter asserted that the phrase ''provides the basis'' means that science that serves as the basis for informing a final significant regulatory action could be all the science considered, relied upon, and included in the administrative record of a rulemaking by the EPA. The EPA agrees with this and clarifies in the final rule that the scope of science that serves as the basis for informing a significant regulatory action is equivalent to the science included in the public docket as part of a rulemaking, but not all of that body of science would typically be considered ''pivotal science.''

D. Applicability of the Rule

In the 2018 proposed rulemaking, the EPA proposed to apply the requirements of this rulemaking on significant regulatory decisions. The EPA then solicited comment on whether the requirements of this rulemaking should apply to (1) other stages of the rulemaking process; (2) a narrower scope of coverage; and (3) certain categories of regulatory actions, such as individual party adjudications, enforcement activities, or permit proceedings or other agency actions. In the 2020 SNPRM, the EPA proposed to expand the applicability of this rulemaking to include influential scientific information.

The EPA received significant comment on the proposed applicability of this rulemaking to significant regulatory decisions and influential scientific information. Some commenters supported the proposed applicability, while other commenters disagreed with it.

A few commenters addressed the potential for expansion or narrowing of the scope of the rule to include other actions in addition to final significant regulatory decisions and influential scientific information. Of the few commenters that explicitly addressed potential expansion beyond the proposed rulemaking, a majority focused on recommendations to include the science underlying Integrated Science Assessments (ISAs) and IRIS assessments. A few commenters expressed support to expand the proposed rulemaking to include one or more of the following: TSCA risk evaluations; CERCLA remedial actions; RCRA corrective actions; as well as assessments and actions under the CWA. Additional comments recommended expansion of the scope of the proposed rulemaking to include enforcement and permitting actions, as well as agency guidance documents. Some commenters supported applying the requirements of this rulemaking to proposed rules and advance notices of proposed rulemakings. Other commenters specifically opposed expanding the proposed rulemaking to include the aforementioned actions. Additionally, some commenters recommended narrowing the scope to only rulemakings subject to the Congressional Review Act or economically significant regulatory actions under E.O. 12866 (*i.e.,* those rules that ''have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities'').

Some of the assessments that commenters suggested should be subject to the requirements of this rulemaking are categorized as influential scientific information. The EPA notes that many assessments categorized as influential scientific information support rulemakings and other actions under several environmental statutes that the EPA administers. For example, the ISA for lead and the IRIS assessment for trichloroethylene have been used in a variety of actions (including those that are not significant regulatory actions) under TSCA, RCRA, and the CAA. IRIS assessments are routinely used under the CAA, RCRA, and CERCLA. By finalizing the scope rule to include influential scientific information, the Agency is applying the applicability of the rule to an important category of scientific assessments that influence a wide range of EPA regulatory actions.

The EPA sees no need to include the proposed rule stage of final significant regulatory actions in the regulatory text because as a practical matter proposed rules must comply with this final rule before being finalized. As a general matter, the EPA does not introduce the studies and analyses it relies on for a rulemaking at the final rule stage. The scientific basis for a rulemaking is provided for public review and comment in the public docket when the proposed rule is issued or, if subsequently added to the docket, through a separate opportunity for public comment. Advance notices of proposed rulemakings are not consistent with the purpose of this rule, given their preliminary nature and frequent focus on soliciting comments on a regulatory issue or approach.

Transparency is important in ensuring that the decisions the EPA makes are based on sound science. The EPA is finalizing the applicability of this rule to significant regulatory actions and influential scientific information because of the potential broad impact of these actions and assessments on American lives and livelihoods. The EPA is not applying this rulemaking to permit proceedings, site-specific actions, or enforcement actions because these actions are typically focused on individual regulated entities.

E. Availability of Dose-Response Data

In the 2018 proposed rule, the EPA proposed to require at 40 CFR 30.5 that ''[w]hen promulgating final significant regulatory decisions, the Agency shall ensure that dose-response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation.'' The EPA received a large number of comments stating that the approach in the 2018 proposed rule would likely preclude the use of valid data and models from consideration as pivotal science. The comments indicated that the proposed requirement to ensure data and models are publicly available in a manner sufficient for independent validation would prevent the use of data and models that include CBI, proprietary data, and PII that cannot be sufficiently de-identified to protect the data subjects, as well as many older studies. In response to such comments, in the 2020 SNPRM, the EPA proposed a modified version of the 2018 proposed regulatory text at 40 CFR 30.5. Proposed 40 CFR 30.5 would allow

agency consideration of studies with restricted access to data and models that have CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects. For all other studies, data and models should be publicly available if the studies were to be used as pivotal regulatory science or pivotal science. In the 2020 SNPRM, the EPA also proposed an alternative. Under the alternative 40 CFR 30.5 proposal, when promulgating significant regulatory decisions or developing influential scientific information, the Agency would, other things equal, give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation either because the information is publicly available or available through tiered access when the data include CBI, proprietary data, or PII and appropriate techniques have been used to reduce the risk of re-identification. In the 2020 SNPRM, the Agency proposed that in developing the final significant regulatory decision or influential scientific information, the EPA would identify those studies that were given greater consideration and provide a short description of why and how greater consideration was given.

A few commenters contended that 40 CFR 30.5 as proposed in the 2018 proposed rule was superior to proposed 40 CFR 30.5 in the 2020 SNPRM and the alternative proposed 40 CFR 30.5 in the 2020 SNPRM. The commenters asserted that privacy or confidentiality should not have priority over transparency. They further asserted that the approaches in the 2020 SNPRM would impose substantial limits on the effect of the rule since privacy, confidentiality, and restricted access are all concepts and practices that inhibit full transparency.

Some commenters supported the categorical approach taken in proposed 40 CFR 30.5 in the 2020 SNPRM in which pivotal science would need to be available for independent validation. A few commenters suggested that it be expanded to apply to all studies, not only those that are pivotal science. Other commenters contended the proposed 2020 SNPRM approach was flawed because it would exclude from consideration valid scientific studies for which the underlying data at the stage required by this regulation are unavailable, regardless of whether the studies have been peer reviewed or would be considered part of the ''best available science'' under the environmental statutes that EPA administers that require the use of ''best available science.'' These commenters stated that such a categorical exclusion is inconsistent with current scientific standards and the requirements of the environmental statutes that the EPA administers. Other commenters noted that there are a variety of reasons, including the age of a study, why the underlying data at the stage required by this rulemaking would not be available, publicly or otherwise, for independent validation.

Some commenters supported and other commenters opposed alternate proposed 40 CFR 30.5 in which the Agency would, all else being equal, give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation. Some commenters stated that this was a reasonable way to consider transparency because studies would be assessed on a case-by-case basis and valid studies would not be categorically excluded. Other commenters did not support alternate proposed 40 CFR 30.5 because they contended there is no scientific justification for a rule that directs the EPA to selectively give greater consideration to certain studies over others based on data availability.

Upon consideration of the comments, the EPA agrees that it is important not to categorically exclude any study because the data underlying a study at the stage required by this rulemaking may not be available for independent validation. Therefore, the EPA is not finalizing the primary proposal in the 2020 SNPRM that would have categorically required that for studies to be considered pivotal science, the underlying data would need to be available for independent validation. However, given that transparency is an important aspect of EPA's regulatory actions and assessments, it should be an important consideration in how the Agency considers pivotal science. As described in 40 CFR 30.5 of the final rule, the EPA will rely on the highest quality, most relevant studies available in determining the potential for hazard due to exposure to a pollutant, contaminant, or substance. Where there is convincing and well substantiated evidence to support a relationship between exposure and effect, the EPA will identify those studies—based on the exposure situation being addressed, the quality of the studies, the reporting adequacy, and the relevance of the endpoints—that would inform a dose-response assessment for those effect endpoints. From that subset, the specific dose-response studies or analyses that drive the requirements or quantitative analyses of an EPA significant regulatory action or influential scientific information will be identified as pivotal science.

Further, the EPA is finalizing the approach that gives greater consideration to pivotal science whose underlying dose-response data are publicly available or available through restricted access. Restricted or tiered access in this final rule means that the underlying dose-response data are available through a data sharing mechanism, such as through an agreement with the originating author or institution, access to a refined or redacted dataset that anonymizes the more sensitive portions of the analyzable dataset, a restricted access data repository or secure data enclave, or some other mechanism (*e.g.,* Data Use Agreements) that allows a qualified subject matter expert access to enough data to support independent validation while still protecting sensitive information.

Some commenters argued that the EPA did not sufficiently explain how it will identify ''pivotal science.'' For example, one commenter stated that the EPA did not explained what it means for a study to ''underly'' [sic] influential scientific information or to ''drive the requirements'' of final significant regulatory actions. Some commenters on the 2018 proposed rule asked for the EPA to clarify in what stage of the review process the Agency would identify pivotal science. In the 2020 SNPRM, the EPA explained, ''under this [proposed] regulation EPA would continue to use standard processes for identifying, evaluating, and reviewing available data, models, and studies. When the Agency has potentially identified multiple key studies or models of similar quality that could drive its subsequent decisions, the Agency will investigate the availability of the underlying data.'' In response to the 2020 SNPRM, one commenter suggested the EPA provide a transparent explanation of how and why studies are determined to be pivotal science over others. A commenter also argued that if the EPA interprets ''pivotal science'' narrowly (*i.e.,* not as all the studies included in the weight of evidence), this would introduce risk of selecting ''pivotal science'' in a biased manner without sufficient accountability. Another commenter recommended that the EPA establish criteria for designating studies as pivotal science.

The EPA disagrees with the proposition that designating a set of key studies as ''pivotal science'' will necessarily be biased or without accountability. The EPA follows an objective, unbiased process for identifying and evaluating scientific

studies and already identifies key or pivotal studies in some of its actions (*e.g.,* IRIS assessments). The EPA intends to issue implementation guidelines and statute-specific rulemakings that will further describe these criteria and how the EPA will identify pivotal science in its assessments and rulemakings. In general, the EPA will rely on the highest quality, most relevant studies available in determining the potential for hazard due to exposure to a pollutant, contaminant, or substance. Where there is convincing and well substantiated evidence to support a relationship between exposure and effect, the EPA will identify a subset of those studies based on the exposure situation being addressed, the quality of the studies, the reporting adequacy, and the relevance of the endpoints that would inform a dose-response assessment for those effect endpoints and drive the requirements and/or quantitative analyses of an EPA final significant regulatory action or influential scientific information will be identified as pivotal science.

Further, the EPA intends to promulgate regulations under the environmental statutes that the EPA administers to further clarify how the Agency will apply the definition of ''pivotal science'' in specific programs authorized under those statutes (*e.g.,* CAA, CWA, SDWA, RCRA, FIFRA, TSCA, EPCRA). The specific criteria for determining ''pivotal science'' may necessarily be specific to the authorizing statute, as well as the significant regulatory action or the influential scientific information. The EPA intends to explain in each significant regulatory action and for influential scientific information how the pivotal studies were identified.

In response to comments on the meaning of ''drive the requirements and/or quantitative analysis,'' these are the studies that are integral to quantitatively characterizing dose-response relationships for the toxicity endpoints that underlie the requirements or analyses of EPA significant regulatory actions or influential scientific information. The EPA may further interpret the meaning of ''drive,'' and describe the process for designating key studies as pivotal science in subsequent implementation guidelines and/or statute-specific rulemakings.

Some commenters stated that the EPA did not explain what was meant by ''other things being equal.'' Some of these commenters requested clarity on what factors in addition to transparency would be considered. Some specific suggestions from commenters include that EPA should give consideration to quality studies that evaluate a range of models, that are scientifically sound for the intended use, and that have study ''characteristics (*e.g.,* sample size, confidence intervals of results, or overall methods validity) [that] may compensate for any lack of full transparency.'' In consideration of these and other public comments, the EPA developed additional factors that clarify specific technical factors that it may consider in balancing study quality and data availability. Although the EPA is prioritizing transparency in pivotal science, the Agency also recognizes that there will be instances where the underlying dose-response data of pivotal science is unavailable for independent validation. In order to ensure that the Agency maintains a strong scientific basis for its decision-making, the availability of underlying dose-response data should be considered as long as other significant technical considerations can provide some level of certainty or confirmation of a study's conclusions, importance, and applicability, even in the absence of maximum transparency. Though EPA's list of factors herein is not exhaustive or exclusive, the EPA has identified several factors in 40 CFR 30.5(d) that balance some of the important technical considerations the EPA will consider in addition to data availability and that are particularly relevant to the stage of the analysis where dose-response data are used. These factors are intended to assist the EPA in determining the consideration to afford to pivotal science with underlying dose-response data that are not available for independent validation. The final rule requirements and the consideration of these factors apply to any data used in characterizing the relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect, regardless of the direction of that effect. Because study quality factors (including soundness, applicability and utility, clarity and completeness, uncertainty and variability, and evaluation and review) would have already been evaluated at an earlier stage in the assessment process (see 40 CFR 30.5(b)), the EPA envisions that at the stage of the evaluation that utilizes the factors described in 40 CFR 30.5(d), the studies to be evaluated would generally be of the highest quality available.

Some of the factors in 40 CFR 30.5(d) are intended to be evaluated for pivotal science with underlying data that are not available for independent validation relative to pivotal science with underlying data that are available for independent validation. For example, when assessing studies, the EPA may determine that greater consideration should be given to a study with underlying data that are unavailable for independent validation when that study is of higher quality compared to a medium-quality study with underlying data that are available for independent validation (factor 1), the conclusions of the significant regulatory action or influential scientific information are or are not highly sensitive to the exclusion of the study for which the underlying data are not available for independent validation (factor 3), the study with data unavailable for independent validation was better fit for the purpose of the EPA assessment (factor 4), or the results of the study for which the underlying data are not available are supported by other scientific evidence, such as mechanistic data (factor 6).

Importantly, the factors in 40 CFR 30.5(d) do not apply to other stages in the assessment process (although they are relevant to determining whether to grant an exemption under 40 CFR 30.7, as further explained below). For example, the consideration for exposures that were conducted at more environmentally relevant exposure concentrations (factor 5) does not suggest that epidemiological studies will automatically be given greater weight than laboratory studies. The EPA will continue to use established guidelines for identifying and integrating evidence and will use the factors in 40 CFR 30.5(d) only when evaluating the data availability requirements of this rule (or when determining whether to grant an exemption under 40 CFR 30.7, as further explained below). In addition, not all of these factors will be applicable to all studies or assessments. For example, some pollutants, chemicals, or substances may have unique scientific considerations (factor 7), such as the valence state of a metal compound or endogenous contributions to internal concentrations, that may not be relevant for other pollutants, chemicals, or substances. Therefore, the weight afforded to each factor by the EPA may vary by assessment, and how those factors were considered will be documented in the assessment. If two studies, one with and one without available data and are relatively equal with respect to the study quality factors in 40 CFR 30.5(b), the study where the underlying data is available will be given greater consideration and the weight of the other study will be based on an assessment of the factors in 40

CFR 30.5(d). In this way, the EPA will balance the importance of transparency with the need to maintain a strong scientific basis for its assessments.

This final rule requires the consideration of the factors in 40 CFR 30.5(d) when assessing pivotal studies for which the dose-response data are not available for independent validation. The EPA may adapt these factors in upcoming statute-specific rulemakings, as appropriate, for significant regulatory actions under the different environmental statutes that the EPA administers. How scientific information is to be considered varies among the different environmental statutes and sometimes within an individual statute. Interpretation of the assessment factors will be tailored to the specific circumstances and the specific environmental statutes.

Some commenters asserted that the 2018 proposed rule and the 2020 SNPRM failed to explain how historical data, which may have been collected under different policies and procedures, will be treated. These commenters noted that underlying dose-response data may have been lost for older studies due to record retention schedules. Some commenters also contended that a significant amount of work would be required to locate, curate, and retrospectively make datasets available for public access.

The EPA intends to determine the extent of the consideration that should be given to pivotal studies lacking available data on a case-by-case basis. The EPA will consider the circumstances specific to each such study when it applies the factors listed in 40 CFR 30.5(d) to that study. The age of the data is not a consideration under 40 CFR 30.5(d), but could be the basis for a 40 CFR 30.7 exemption request.

Some commenters stated that the EPA should not have the rulemaking apply retrospectively to studies given the potential difficulty accessing, reviewing, and making data available that were not originally intended to be disseminated, as would be required by this rulemaking. These commenters requested that the EPA apply the rulemaking provisions only to data and models underlying studies generated after the promulgation of this rule.

This final rule applies prospectively to significant regulatory actions and influential scientific information and has no retrospective effect on existing (*i.e.,* completed) significant regulatory actions or influential scientific information. For future, significant regulatory actions and influential scientific information, the final rule applies equally to all dose-response data underlying studies used as pivotal science, regardless of when the study or the data was created. Scientific transparency is important regardless of the age of the study or the dose-response data.

Some commenters contended that a substantial amount of work would be required in order to make data underlying studies available for independent validation, but that the EPA has not identified a responsible party for this work, nor has it made clear the timelines, electronic data sharing mechanisms, or how public reporting of such availability would be achieved, archived, and maintained over time. The EPA would like to emphasize that this final rule does not impose requirements on any entity outside of the EPA. This is a rule of internal procedures and does not direct or require any outside entity or the EPA to establish data sharing mechanisms. Further, the final rule does not require the EPA to collect, store, or publicly disseminate dose-response data underlying pivotal science.

Some commenters asserted that reproducing findings across similar studies is more informative than reanalyzing the data from a single study. Such commenters noted that confidence in the study findings is best gained when different groups are studying the same thing or are conducting similar studies. They asserted that the study results could then be averaged, compared, and further analyzed. One commenter noted that the ability to reanalyze the data from a study with very poor scientific quality does not strengthen the quality of the study. Commenters contended that reproducing studies (*i.e.,* producing something that is very similar to that research, but it is in a different medium or context) is generally viewed as a more informative and resource efficient approach to validation of research than reanalyzing the data of a particular study. Some commenters contended that reanalysis of the data and models underlying studies is not how to determine the quality of a study; rather, there are other key aspects of studies that are integral to assessing the quality of a study.

Other commenters supported the proposed requirement for independent validation by reanalysis of data and models underlying studies because they believe this is key to determining whether the science is accurate and of high quality. Some commenters contended that by reanalyzing the underlying data and models, independent researchers can evaluate the myriad of choices and assumptions the original researchers have made regarding the data and statistical models and the potential introduction of any sources of bias.

While the availability of dose-response data underlying a study in a manner sufficient for independent validation is an important component of determining the level of consideration to afford a study, the EPA agrees that availability by itself is not sufficient to determine study quality. As explained in 40 CFR 30.5(b), the EPA will use existing factors (including soundness, applicability and utility, clarity and completeness, uncertainty and variability, and evaluation and review) to evaluate study quality. Subsequently, after identifying the highest quality, most relevant studies that would inform a dose-response assessment and identifying the availability of pivotal science, the EPA would consider the additional applicable factors in 40 CFR 30.5(d) when determining the level of consideration to give pivotal science where the underlying dose-response data are not available for independent validation. Further, although the EPA agrees with commenters that meaningful insights can be obtained through similar studies in different media or context, the EPA continues to find that independent validation of the study findings and conclusions driving the EPA's dose-response assessments would provide important information. As detailed in Section III.A.1 of this preamble, there is scientific support for the usefulness of reanalyzing data, and the EPA finds this to be especially true for data that drive the quantitative requirements or analyses of EPA significant regulatory actions or influential scientific information. Implementation of this rule will increase transparency and, thus, the opportunity for independent subject matter experts to validate pivotal science, and as the dose-response data are better understood the public will, if they so choose, be able to more effectively comment, engage, and hold the EPA accountable during the development of future significant regulatory actions and influential scientific information.

F. Proposed 40 CFR 30.6

In the 2018 proposed rule, the EPA proposed requirements at 40 CFR 30.6 specific to dose-response data and models. These proposed requirements directed the EPA to describe and document the assumptions and methods it used; to evaluate the appropriateness of using default assumptions, including assumptions of a linear, no threshold dose-response; to explain the scientific

basis for each model assumption used; and to show the sensitivity of the modeled results to alternative assumptions. These proposed requirements also directed the EPA to give explicit consideration to high quality studies that explore a broad class of parametric dose-response models, non-parametric models that incorporate fewer assumptions, various threshold models, and models that investigate factors that might account for spatial heterogeneity.

The EPA received significant comment on the 2018 proposed rule regarding the proposed 40 CFR 30.6 requirement that the EPA evaluate the appropriateness of using default assumptions, ''including assumptions of a linear, no threshold dose-response.'' The vast majority of commenters asserted that the EPA should not focus the requirement to evaluate the appropriateness of using default assumptions specifically on linear, no threshold dose-response. In the 2020 SNPRM, in response to these comments, the EPA proposed a variation of the regulatory text which did not include the phrase ''including assumptions of a linear, no threshold dose-response,'' because this could imply that the regulation is specific to those particular assumptions.

The EPA also received significant comment on the 2018 proposed rule about the proposed 40 CFR 30.6 requirement to clearly explain the scientific basis for each model assumption used and to present analyses showing the sensitivity of the modeled results to alternative assumptions. Most commenters contended that such a requirement would be overly burdensome and unnecessary. They recommended that the EPA should present sensitivity analyses only on the most significant assumptions.

Considering these comments, in the 2020 SNPRM, the EPA clarified that the use of the terms ''model assumptions,'' ''assumptions'' and ''models'' in the proposed regulatory text at 40 CFR 30.6 apply to the critical assumptions that drive the model's analytic results, not to each assumption used in the model. The EPA's proposed revision of the 40 CFR 30.6 regulatory text reflected this clarification.

After considering comments on both the 2018 proposed rule and the 2020 SNPRM, the EPA has determined that this rule should apply to dose-response data rather than dose-response data *and models.* Given the specificity of 40 CFR 30.6 to dose-response data and models, and in particular dose-response models, the EPA is not finalizing 40 CFR 30.6. The EPA is adapting one provision of 40 CFR 30.6 as a factor in 40 CFR 30.5 in determining the consideration to afford pivotal science for which the dose-response data are not available for independent validation. Specifically, the EPA is finalizing as a factor in 40 CFR 30.5 the consideration that the EPA would give to high quality studies that explore a broad class of parametric dose-response models, non-parametric models that incorporate fewer assumptions, various threshold models, and models that investigate factors that might account for spatial heterogeneity.

Further, because the EPA is not finalizing any part of the provision that is specific to assumptions and methods associated with dose-response models, comments on the proposed requirements related to these issues are moot. However, while the EPA is not finalizing the provisions in 40 CFR 30.6 that include the term uncertainty, the EPA is responding to these comments because the term uncertainty is used in 40 CFR 30.5. The EPA is also responding to comments on the proposed 40 CFR 30.6 provision incorporated as part of 40 CFR 30.5.

Some commenters contended that the EPA's use of the term ''uncertainty'' at 40 CFR 30.6 is vague. A few other commenters contended that the EPA should include specific requirements in 40 CFR 30.6 as to the scope of an analysis of uncertainty. The EPA disagrees with the suggestion that the term ''uncertainty'' is vague or that there is significant ambiguity about what should be in the scope of a characterization of uncertainty. The characterization of uncertainty is a key factor in the assessments that the EPA conducts. It is a component of various EPA guidelines (*e.g., Framework for Human Health Risk Assessment to Inform Decision Making,* Ref. 36) that the EPA relies upon in conducting its assessments. The scope of the uncertainty analyses that the EPA conducts necessarily varies across assessments and actions. The intent of this regulation is not to force uncertainty analyses into a one-size-fits-all approach, as that is not practical, good policy, or good science. Thus, a regulation of internal procedures, such as this one, does not require a regulatory definition for a term that is already a key component of current EPA practices and guidelines and EPA's assessment process.

Several commenters contended that the proposed 40 CFR 30.6 requirement that the EPA give explicit consideration to high quality studies that explore a broad range of parametric dose-response or concentration-response models and to non-parametric models that incorporate fewer assumptions could force the EPA into situations in which it applies dose-response model(s) that are not appropriate for the data being assessed. The EPA notes that the final regulatory text in 40 CFR 30.5 does not require that a specific type of dose-response model be applied to a particular situation. Rather, in determining the consideration to afford pivotal science for which the dose-response data are not available for independent validation, the EPA will evaluate, as appropriate, the extent to which the study considered a broad range of parametric dose-response or concentration-response models, a robust set of potential confounding variables, nonparametric models that incorporate fewer assumptions, various threshold models across the dose or exposure range, and models that investigate factors that might account for spatial heterogeneity.

G. Administrator's Exemption

In the 2018 proposed rule, the EPA proposed that the Administrator could grant case-by-case exemptions to the requirements in proposed 40 CFR part 30 when compliance with those requirements is impracticable (proposed 40 CFR 30.9). In the 2020 SNPRM, the EPA modified proposed 40 CFR 30.9 to be consistent with other changes proposed in the 2020 SNPRM, such that the Administrator could grant case-by-case exemptions to the requirements in proposed 40 CFR part 30 under specific conditions for which compliance with the requirements in proposed 40 CFR part 30 is impracticable.

Some commenters supported the Administrator's exemption provision in proposed 40 CFR 30.9 while others opposed it. Commenters expressing support for the exemption provision noted that exemptions may be needed to account for lawful and reasonable restrictions on underlying data and models. Commenters expressing opposition to the exemption provision raised concerns about the Administrator granting exemptions from the requirements in proposed 40 CFR part 30. These commenters contended that the Administrator may lack the scientific expertise to make the appropriate exemption decisions and that the Administrator, as a political appointee, could be biased. Some public commenters recommended that the exemption process require formal consultation with EPA career scientists, the EPA's SAB, or another Agency advisory committee.

The EPA also received comment on the following proposed conditions

under which the Administrator could grant an exception in the 2020 SNPRM: Technological barriers render sharing of the data or models infeasible; the development of the data or model was completed or updated before the effective date of the final rule; or making the data and models available would conflict with laws governing privacy, confidentiality, CBI, or national security. Some commenters supported the condition that would allow the Administrator to grant an exemption based on the age of a study, noting that older studies may not have been conducted with the intention of providing access to underlying data and models for independent validation, particularly at the stage of data and models proposed in the 2020 SNPRM. Other commenters opposed this condition, contending that exempting studies based on the age of the study is unnecessary and undermines the goal of increasing transparency in the development of regulatory decisions. Some commenters noted it may be prohibitively expensive for researchers to make their data and models available.

The EPA finds that these comments have merit, in part. The Agency agrees with retaining the Administrator's exemption provision because there are conditions under which compliance with the requirements in 40 CFR part 30 might be impracticable. For example, the underlying dose-response data for some studies, particularly older studies, may not be readily publicly available because of the technological barriers to data sharing (*e.g.,* differences in data storage devices or data retention practices) that existed when they were developed. As a result, the EPA is finalizing the Administrator's exemption provision as proposed in the 2020 SNPRM, with additional conditions described here. Due to other changes described in this preamble, the Administrator's exemption provision, which was previously in 40 CFR 30.9 in the 2018 proposed rule and the 2020 SNPRM, is now 40 CFR 30.7 in the final rule.

The EPA does not agree with the comments regarding the role of the Administrator in determining whether to grant an exemption and finds that the Administrator is the appropriate decision maker in this context. To ensure that the Administrator's decision is appropriately transparent, in the final rule the EPA has included a provision in 40 CFR 30.7 that requires the Agency to document the rationale for any exemptions granted by the Administrator in the significant regulatory action or influential scientific information. This documentation would typically be provided as part of the proposed rulemaking, given that it would be part of the decision concerning what is the pivotal science for the rule. Regardless of what is provided in the proposed rule stage of the rulemaking, the final rulemaking will provide clear documentation.

Some commenters and the EPA's SAB (Ref. 27) also requested that the EPA include criteria that the Administrator will consider when determining whether to grant exemptions from the requirements in 40 CFR part 30. The EPA finds that these comments have merit and is including additional criteria in 30 CFR 30.7 that may be used by the Administrator when he or she is determining whether greater consideration should be afforded to pivotal science for which the underlying dose-response data are not available in a manner sufficient for independent validation. As a result, the Administrator may also determine that greater consideration is warranted when a third party has independently validated the underlying dose-response data through reanalysis or when the EPA's evaluation of the factors in 40 CFR 30.5(d) indicate that full consideration of the pivotal science is justified.

To assist the Administrator in determining whether to grant an exemption, the EPA program or Region responsible for the significant regulatory action or influential scientific information and public commenters can provide input when the Administrator is considering an exemption. The EPA will document the rationale for the Administrator's exemption in the significant regulatory action or influential scientific information. The EPA is confident that the above criteria provide sufficient clarity and boundaries for the Administrator to consider when granting an exemption under 40 CFR 30.7.

H. Peer Review

In the 2018 proposed rule and the 2020 SNPRM, the EPA proposed to require independent peer review on pivotal regulatory science and pivotal science. The EPA also proposed to require that the Agency ask peer reviewers to opine on the strengths and weaknesses of the EPA's justifications for the assumptions used in models.

Some commenters on the 2018 proposed rule and 2020 SNPRM specifically asked why the EPA would need to peer review health and scientific studies and scientific literature that had already undergone independent peer review. They stated that the EPA failed to explain why existing peer review requirements and mechanisms are insufficient. Such commenters also noted that in addition to being duplicative and unnecessary, the proposed requirement would cause unnecessary delays in the EPA actions and would result in increased costs for the Agency. One commenter noted that the EPA already has policies in place for peer review and referred to the EPA's Peer Review Handbook (Ref. 44). Another commenter stated that, while it is certainly best practice to consider only science that has been independently peer reviewed when making regulatory decisions, that does not necessitate independent peer review by the EPA. The commenter noted that most scientific bodies and publications—including *Nature, Science,* the Bipartisan Policy Center, and *Proceedings of the National Academy of Sciences*—employ some of the most robust peer review practices and that they already apply to the types of studies which the proposed rule would require the EPA to peer review anew. Some commenters also stated that the proposed peer review requirements specific to assumptions used in models suggest that the 40 CFR 30.7 regulatory text would require that the EPA conduct peer review of the proposed Agency action itself, rather than of the science underlying that action. One of the commenters contended that it is entirely unclear how peer review could be applied to EPA's reasoning itself, rather than the pivotal science supporting the regulatory decision.

The EPA finds that these comments have merit, in part. However, in this rule, the EPA is not changing the pre-existing requirements of the OMB Final Information Quality Bulletin for Peer Review (Ref 8). The preamble of the Bulletin states that ''the intensity of peer review is highly variable across journals'' and ''prior peer review and publication is not by itself sufficient grounds for determining that no further review is necessary'' (Ref. 8). Peer review does not typically include reanalysis of the underlying data (*i.e.,* the proper stage of data where the data that are ready to be analyzed to extract relevant information) and, thus, peer review is not considered a replacement for the data availability requirements of this rule.

The EPA is, therefore, finalizing the language at 40 CFR 30.6 (formerly 40 CFR 30.7 in the 2018 proposed rule and the 2020 SNPRM) to clarify that the Agency will evaluate whether or not to initiate peer review, consistent with the OMB Final Information Quality Bulletin for Peer Review (Ref. 8) and the EPA's Peer Review Handbook (Ref. 44), of

individual studies identified as pivotal science if the studies have already undergone journal peer review. If the Agency conducts peer review on pivotal science, the EPA shall ask peer reviewers to articulate the strengths and weaknesses of the justification for the assumptions applied in analyzing dose-response data and the implications of those assumptions for the results.

I. Changes to 40 CFR 30.4 ''What requirements apply to EPA's use of studies in significant regulatory actions?''

In the 2018 proposed rule, the EPA proposed to require at 40 CFR 30.4 that ''EPA shall clearly identify all studies (or other regulatory science) relied upon when it takes any final action. The EPA should make all such studies available to the public to the extent practicable.'' Some commenters expressed concern that proposed 40 CFR 30.4 would permit the Agency to exclude valid studies from consideration on the basis of the availability of underlying data or models. Another commenter noted that this section would apply to any final agency action, rather than regulatory decisions. In response to these comments, the EPA notes that this section does not require the EPA to exclude studies from consideration when developing final significant regulatory actions either on the basis of the availability of underlying data or models, or depending on the practicability of making these studies available to the public.

The EPA agrees with the commenter that the scope of 40 CFR 30.4 should be limited to significant regulatory actions, which are defined in 40 CFR 30.2 as ''final regulations determined to be 'significant regulatory actions' by the Office of Management and Budget pursuant to Executive Order 12866.'' The EPA is finalizing additional changes to the title and body of 40 CFR 30.4 by using terms defined in 40 CFR 30.2. In the title of 40 CFR 30.4, the EPA is replacing ''taking final action'' with ''significant regulatory actions'' to improve clarity and specificity, since the latter term is defined. In the body of 40 CFR 30.4, the EPA is replacing ''all studies (or other regulatory science) relied upon when it takes any final agency action'' with ''science that serves as the basis for informing a significant regulatory action'' to improve specificity, since the latter language is defined; replacing ''should'' with ''shall;'' ''studies'' with ''science that serves as the basis for informing a significant regulatory action'' to improve specificity, since the latter term is defined; and ''available to the public'' with ''publicly available'' to improve specificity, since the latter term is defined. Together, these changes are meant to clarify that the requirements of 40 CFR 30.4 are consistent with the EPA's existing practice of making science that serves as the basis for informing a significant regulatory action available in the public docket as part of the rulemaking.

J. Benefits and Costs

In the 2018 proposed rule, as part of its E.O. 12866 and E.O. 13563 reviews, the EPA stated that the benefits of the proposal justify the costs. The EPA's rationale was that the rule would facilitate expanded data sharing and exploration of key data sets, improve the ability to independently validate analyses underlying significant regulatory actions, and would be implemented in a cost-effective way. The 2020 SNPRM did not provide additional characterizations of benefits and costs. A number of commenters noted that the EPA did not provide an economic assessment to support the Agency's benefit-cost claims. Commenters also noted that the EPA did not characterize costs to the Agency, including administrative costs to ascertain the public availability of underlying data, costs for additional analyses required, and costs to ensure that PII and CBI are not disclosed. Other commenters noted that the EPA had not adequately explained the benefits of this rule, including enabling increased secondary analyses by third party researchers.

The EPA agrees that neither the 2018 proposed rule nor the 2020 SNPRM included a characterization of costs to the Agency. The EPA emphasizes that this is a rule of internal procedure promulgated under the EPA's housekeeping authority. However, the EPA has identified some incremental costs that the Agency may incur as a result of this final rule. As stated in Section III.A.2 of this preamble, the EPA will continue its current practice of conducting extensive review of scientific studies during the development of significant regulatory actions and influential scientific information. The additional procedures required by this rule apply only to pivotal science, which is a subset of the total number of studies that the EPA would evaluate. Given the costs of the current robust process for identifying and reviewing scientific studies and documentation that are existing Agency practice, as well as that the determination of dose-response data availability is limited to pivotal science underlying significant regulatory actions and influential scientific information, the EPA anticipates that the incremental costs of this rule will be small. The Agency may also incur other administrative costs to perform analyses and evaluations to support activities such as exemption decisions made by the Administrator, and documenting these or other decisions made pursuant to the requirements of the final rule. Again, the Agency anticipates that the incremental costs for these activities will be small relative to current administrative costs for developing significant regulatory actions or influential scientific information. Finally, this final rule does not require the EPA to disclose or host data, but to determine if dose-response data are available and to give greater consideration to those studies for which such data are available. Hence, this rule does not impose costs on the EPA or any other party to make data available, including costs to ensure that PII and CBI are not disclosed. The Agency may opt, at its discretion, to incur the costs associated with making data available when it is in the public interest to do so, but that will be decided on a case-by-case basis and is not a requirement of the final rule.

The EPA also agrees that the benefits of the rule were not fully characterized in the 2018 proposed rule or the 2020 SNPRM. The EPA emphasizes, however, that this is a rule of internal procedure promulgated under the EPA's housekeeping authority. As discussed in Section III.A.1 of this preamble, the main benefits of this rule spring from greater transparency in significant regulatory actions and influential scientific information. By placing greater emphasis on the availability of dose-response data underlying pivotal science, the rule will allow for greater scientific scrutiny as EPA decision makers are developing significant regulatory actions and influential scientific information and increases the likelihood that any errors will be identified and corrected. Greater transparency is also inherently valuable as a principle of good government and provides benefits to the public at large, including reducing the risk of errors in EPA analyses and in the science such analyses rely upon. The ability for independent subject matter experts to validate pivotal science will facilitate more effective comment and engagement with the public during development of future significant regulatory actions and influential scientific information.

Some commenters further argued that the EPA failed to account for costs external to the EPA as consequence of

this rule, including costs to third party researchers and their institutions to make their raw data available and protect PII/CBI through data-masking, de-identification, or deposition in public data repositories. The EPA disagrees with the argument that this rule would impose costs on third-party researchers. This is a rule of internal procedure that does not impose requirements on any party other than the EPA. This rule imposes no costs on researchers or their institutions, and the EPA will consider and evaluate all relevant and appropriate science in its significant regulatory actions and influential scientific information. The EPA recognizes that researchers and other third parties may voluntarily consider the EPA's position on data availability, as described in this rule, as they make their own decisions about how to conduct research and the extent to which they make data and models available. Researchers may choose to make more data and models available, but the EPA recognizes that these parties will weigh their own benefits and costs and make choices that they deem appropriate.

Some commenters argued the 2018 proposed rule and the 2020 SNPRM would impose costs on third parties because it would prohibit the EPA from using necessary science where the underlying data and models are not publicly available, which would prevent the EPA from meeting its statutory obligations and performing its mission of protecting human health and the environment. Some commenters also contended that the proposed rule requirements would impose costs to the public by delaying EPA regulatory actions that protect human health and the environment.

As described earlier, the EPA acknowledges and agrees with commenters that there may be pivotal science where the underlying data are not publicly available or available through restricted access. The final rule is limited to dose-response data and, as no studies are categorically excluded from consideration, the EPA will continue to rely on the full body of the highest quality, most relevant studies available in determining the potential for hazard due to exposure to a pollutant, contaminant, or substance. Consistent with the requirements of this rule, the EPA will identify a subset of those studies based on the exposure situation being addressed, the quality of the studies, the reporting adequacy, and the relevance of the endpoints that would inform a dose-response assessment, and will give greater consideration to pivotal science for which the underlying dose-response data are available. The EPA disagrees with commenters that the requirements of this rule will result in any meaningful delay in promulgating regulations. While this final rule requires the Agency to evaluate the availability of dose-response data for pivotal science, the incremental burden to the Agency to carry out these requirements is expected to be small given (1) the extensive scientific review the EPA already conducts regularly and (2) that the requirement is limited to pivotal science (*i.e.,* typically a small, though highly important, subset of the studies the EPA would review). Further, with this final rule, the EPA is maintaining language in 40 CFR 30.3 stating that the statutes that the EPA administers, or their implementing regulations, will control in the event of any conflicts with the requirements of this rule. The Agency will continue to comply with and abide by the requirements in those statutes and implementing regulations, including regulatory deadlines.

K. Proposed 40 CFR 30.8 ''How is EPA to account for cost under this subpart?''

In 2018, the EPA proposed in 40 CFR 30.8 that ''EPA shall implement the provisions of this subpart in a manner that minimizes costs.'' A number of commenters argued that this statement was vague and that the 2018 proposed rule neither explained what costs this rule would incur, nor how they would be minimized. One commenter further raised concern that, in order to minimize costs, proposed 40 CFR 30.8 may require the EPA to exclude valid data from consideration rather than take potentially expensive steps to protect CBI, proprietary data, and PII. Still other commenters interpreted proposed 40 CFR 30.8 as requiring the EPA to base its final significant regulatory actions and influential scientific information on cost. Commenters expressed concern that this would be at the exclusion of considerations such as the best available science and public health. A commenter further argued that the EPA does not have the statutory authority to base its assessment of science on cost without consideration of public health and environmental costs and benefits and privacy-related costs and benefits, and that doing so would be irrational and arbitrary.

As explained in Section III.J of this preamble, this rule of internal procedure is anticipated to incur small incremental costs related to the additional review of data availability, as compared to the Agency's existing costs for extensive review and documentation as part of the development of significant regulatory actions and influential scientific information. In consideration of the public comments, however, the EPA is not finalizing proposed 40 CFR 30.8 ''How is EPA to account for cost under this subpart?'' This rule is not intended to require the EPA to exclude valid data from consideration on the basis of cost, nor interpret the EPA's statutory authority to consider costs in significant regulatory actions or influential scientific information. Given the EPA's existing commitment to fulfill its duties in a cost-effective manner, the EPA has determined not to finalize proposed 40 CFR 30.8.

IV. References

The following is a listing of the documents that are specifically referenced in this notice. The docket includes these documents and other information considered by EPA, including documents referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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V. Statutory and Executive Orders Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket. The EPA does not anticipate that this rulemaking will have an economic impact on regulated entities.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not subject to Executive Order 13771 because this final rule is a rulemaking of agency organization, procedure, or practice.

C. Paperwork Reduction Act (PRA)

This action does not contain any information collection activities and therefore does not impose an information collection burden under the PRA.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. This action does not regulate any entity outside the Federal Government.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' within the meaning of Executive Order 13211. It is not likely to have a significant adverse effect on the supply, distribution or use of energy, and it has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs (OIRA).

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard.

L. Congressional Review Act (CRA)

This rule is exempt from the CRA because it is a rule of agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties.

List of Subjects in 40 CFR Part 30

Environmental protection, Administrative practice and procedure, Reporting and recordkeeping requirements.

Andrew Wheeler,
Administrator.

■ For the reasons set forth in the preamble, the EPA is adding 40 CFR part 30 to read as follows:

PART 30—TRANSPARENCY IN SIGNIFICANT REGULATORY ACTIONS AND INFLUENTIAL SCIENTIFIC INFORMATION

Sec.

Authority: 5 U.S.C. App.; Pub. L. 98–80, 84 Stat. 2086.

§ 30.1 What is the purpose of this part?

This part directs the EPA to give greater consideration to pivotal science when the underlying dose-response data are available in a manner sufficient for independent validation.

§ 30.2 What definitions apply to this part?

For the purposes of this part:

Data means the set of recorded factual material commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as keystroke or coding errors, have been removed and that is capable of being analyzed by either the original researcher or an independent party.

Dose-response data means the data used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect.

Independent validation means the reanalysis of study dose-response data by subject matter experts who have not contributed to the development of the study to evaluate whether results similar to those reported in the study are produced.

Influential scientific information means scientific information the Agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.

Pivotal science means the specific dose-response studies or analyses that drive the requirements or quantitative analyses of EPA significant regulatory actions or influential scientific information.

Publicly available means lawfully available to the general public from Federal, state, or local government records; the internet; widely distributed media; or disclosures to the general public that are required to be made by Federal, state, or local law. The public must be able to access the information on the date of publication of the proposed rule (or, as appropriate, a supplemental notice of proposed rulemaking, or notice of availability) for the significant regulatory action or on the date of dissemination of the draft influential scientific information for public review and comment.

Reanalyze means to analyze exactly the same dose-response data to determine whether a similar result emerges from the analysis by using the same methods, statistical software, models, or statistical methodologies that were used to analyze the dose-response data, as well as to assess potential analytical errors and variability in the underlying assumptions of the original analysis.

Science that serves as the basis for informing a significant regulatory action means studies, analyses, models, and assessments of a body of evidence that provide the basis for EPA significant regulatory actions.

Significant regulatory actions means final regulations determined to be ''significant regulatory actions'' by the Office of Management and Budget pursuant to Executive Order 12866.

§ 30.3 How do the provisions of this part apply?

(a) The provisions of this part apply to science that serves as the basis for informing a significant regulatory action or influential scientific information, as well as to dose-response data underlying pivotal science, regardless of the source of funding or identity of the party conducting the science. The provisions of this part apply to significant regulatory actions for which a proposed rule was published in the **Federal Register** after January 6, 2021 and influential scientific information submitted for peer review after January 6, 2021.

(b) The provisions of this part do not apply to physical objects (like laboratory samples), drafts, and preliminary analyses, and influential scientific information or pivotal science that meet one or more of the exemptions identified in Section IX of the OMB Final Information Quality Bulletin for Peer Review. In the event the procedures outlined in this part conflict with statutes the EPA administers, or their implementing regulations, the statutes and regulations will control. Except where explicitly stated otherwise, the provisions of this part do not apply to any other type of Agency action, including individual party adjudications, enforcement activities, site-specific actions, or permit proceedings.

§ 30.4 What requirements apply to the EPA's use of studies in significant regulatory actions?

The EPA shall clearly identify the science that serves as the basis for informing a significant regulatory action. The EPA shall make all such science that serves as the basis for informing a significant regulatory action publicly available to the extent permitted by law.

§ 30.5 What requirements apply to the EPA's use of dose-response data underlying pivotal science?

(a) When promulgating a significant regulatory action or developing influential scientific information that relies on dose-response data, the Agency shall follow best practices to evaluate potential links between exposure to a pollutant, contaminant, or substance and the effect and the nature of the dose-response relationship.

(b) The EPA will use the following factors to assess the quality of studies identified in the systematic review: soundness, applicability and utility, clarity and completeness, uncertainty and variability, and evaluation and review. The EPA will rely on the highest quality, most relevant studies in determining the potential for hazard due to exposure to a pollutant, contaminant, or substance. Where there is convincing and well-substantiated evidence of a relationship between exposure and effect, the EPA will identify those studies based on the exposure situation being addressed, the quality of the studies, the reporting adequacy, and the relevance of the endpoints that would inform a dose-response assessment for those effect endpoints. From the subset in the preceding sentence, the specific dose-response studies or analyses that drive the requirements, quantitative analyses, or both of an EPA significant regulatory action or influential scientific information will be identified as pivotal science.

(c) The EPA shall give greater consideration to pivotal science where the underlying dose-response data are publicly available in a manner sufficient for independent validation. The Agency shall also give greater consideration to pivotal science based on dose-response data that include confidential business information, proprietary information or personally identifiable information if these data are available through restricted access in a manner sufficient for independent validation. For pivotal science where there is no access to dose-response data, or access is limited, the Agency may still consider these studies but will give them lesser consideration unless the Administrator grants an exemption under § 30.7. The Agency will identify the pivotal science that was given lesser consideration and provide a short description of why lesser consideration was given.

(d) In determining the degree of consideration to afford pivotal science for which the dose-response data are not available for independent validation, the EPA shall consider the following factors and any other relevant factors, as applicable:

(1) The quality of the study relative to other studies for which the dose-response data are available;

(2) The extent to which there are other studies for which the dose-response data are available;

(3) The sensitivity of the conclusions in the significant regulatory action or influential scientific information based on the use of the study;

(4) The extent to which the study is fit for the purpose or intended use relative to other pivotal science for which the dose-response data are available;

(5) The use of exposures or doses in a range and duration that is relevant for the intended use and that minimizes the need for extrapolations;

(6) The extent to which the study is supported by other scientific evidence;

(7) The extent to which the study accounted for unique scientific considerations;

(8) The extent to which the study minimizes the use of defaults and assumptions, uses appropriate and strong statistical methods, and includes a robust representation of uncertainty and confidence intervals; and

(9) The study's consideration of a broad range of parametric dose-response or concentration-response models, a robust set of potential confounding variables, nonparametric models that incorporate fewer assumptions, various threshold models across the dose or exposure range, and models that investigate factors that might account for spatial heterogeneity.

(e) The EPA shall also describe critical assumptions and methods used in its dose-response assessment and shall characterize the variability and uncertainty of the assessment. The EPA shall evaluate the appropriateness of using default assumptions on a case-by-case basis. The EPA shall clearly explain the scientific basis for critical assumptions used in the dose-response assessment that the EPA relied on for the significant regulatory action or influential scientific information.

(f) Where the Agency is making dose-response data publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national security. Dose-response data is considered ''publicly available in a manner sufficient for independent validation'' when it includes the information necessary for the public to understand, assess, and reanalyze findings and may include, for example:

(1) Data (data would be made available subject to access and use restrictions);

(2) Associated protocols necessary to understand, assess, and extend conclusions;

(3) Computer codes and models involved in the creation and analysis of such information;

(4) Recorded factual materials; and

(5) Detailed descriptions of how to access and use such information.

(g) The provisions of this section apply to dose-response data underlying studies that are pivotal science, regardless of who funded or conducted the studies. The Agency shall make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national security is not possible.

§ 30.6 What role does independent peer review have in this part?

The EPA shall conduct independent peer review consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review and the exemptions described therein. The EPA will evaluate whether or not to conduct additional peer review of individual studies identified as pivotal science if the studies have already undergone journal peer review. Because transparency in pivotal science includes addressing issues associated with assumptions used in analyzing dose-response data, the EPA shall ask peer reviewers to articulate the strengths and weaknesses of the justification for the assumptions applied and the implications of those assumptions for the results.

§ 30.7 May the EPA Administrator grant exemptions to this part?

(a) The Administrator may grant an exemption to this part for a study on a case-by-case basis if he or she determines that greater consideration is warranted because:

(1) Technological or other barriers render sharing of the dose-response data infeasible;

(2) The development of the dose-response data was completed or updated before January 6, 2021;

(3) Making the dose-response data available would conflict with laws and regulations governing privacy, confidentiality, confidential business information, or national security;

(4) A third-party has conducted independent validation of the study's underlying dose-response data through reanalysis; or

(5) The factors used in determining the consideration to afford to the pivotal science indicate full consideration is justified.

(b) When making a decision to grant an exemption, the Administrator may consider input from EPA staff and public commenters. The EPA shall document the rationale for exemptions granted by the Administrator in the significant regulatory action or influential scientific information.

[FR Doc. 2020–29179 Filed 1–5–21; 8:45 am]

BILLING CODE 6560–50–P

AGENCY FOR INTERNATIONAL DEVELOPMENT

48 CFR Chapter 7

RIN 0412–AA86

Leave and Holidays for U.S. Personal Services Contractors, including Family and Medical Leave; Corrections

AGENCY: Agency for International Development.

ACTION: Correcting amendments; final rule.

SUMMARY: On October 16, 2020, the U.S. Agency for International Development (USAID) issued a final rule revising provisions of the AID Acquisition Regulation (AIDAR) that pertain to the General Provision contract clause 5, entitled ''Leave and Holidays'' for U.S. personal services contractors (USPSCs.) This document corrects typographical errors in the final rule by revising the text of clause 5, adding the effective dates in the titles of clauses 6 and 16, and revising the authority citation.

DATES: Effective January 6, 2021.

FOR FURTHER INFORMATION CONTACT: Richard E. Spencer, Procurement Analyst, by phone at 202–916–2629, or email at *rspencer@usaid.gov.* All communications regarding this rule must cite AIDAR RIN No. 0412–AA86.

SUPPLEMENTARY INFORMATION: USAID is correcting errors in the final rule entitled ''Leave and Holidays for U.S. Personal Services Contractors, including Family and Medical Leave,'' under AIDAR 48 CFR chapter 7, appendix D, which was published in the **Federal Register** on October 16, 2020 (85 FR 65734). This document corrects the following typographical errors in AIDAR appendix D. In section 12 clause 5, the title is revised to remove italics, and the last sentence of paragraph (a)(3) is revised because the final rule mistakenly included the word ''either'' twice, making the application of the sub-paragraphs (i) and (ii) illogical and impossible to apply. This document corrects the construction of this sentence in paragraph (a)(3) to ensure only one of the two sub-paragraphs (i) or (ii) may apply, and by using the matching terminology for ''exceptional circumstances'' that appears earlier in the paragraph. In the titles for clauses 6, ''Differential and Allowances,'' and 16, ''Termination'', the effective dates missing from the final rule are inserted for each clause. Lastly, the final rule mistakenly included an instruction to add a parenthetical authority citation at the end, unnecessarily creating a double citation. This document instead revises

Exhibit B

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

April 24, 2020

EPA-SAB-20-005

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Science Advisory Board (SAB) Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled *Strengthening Transparency in Regulatory Science*

Dear Administrator Wheeler:

As part of its statutory duties, the EPA Science Advisory Board (SAB) may provide advice and comment on the scientific and technical basis of certain planned EPA actions. The Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA) requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations provided to any other federal agency for formal review and comment, together with relevant scientific and technical information on which the proposed action is based. The SAB may then provide advice and comments on the adequacy of the scientific and technical basis of the proposed action. At its May 31, 2018 public meeting, the chartered SAB identified the proposed rule titled *Strengthening Transparency in Regulatory Science* (Proposed Rule) as a planned action that merited review. In April 2019, the SAB Work Group on Planned Actions for SAB Consideration of the Underlying Science recommended that the SAB review the Proposed Rule and at its public meeting on June 5-6, 2019, the SAB elected to review the scientific and technical basis of the Proposed Rule. Subsequent to the June meeting, a work group of chartered SAB members was formed to carry out the review. Members of this work group then took the lead in SAB deliberations on this topic at a public teleconference held on January 21, 2020. On March 3, 2020, EPA released a Supplemental Notice of Proposed Rulemaking (SNPRM), which contains additional information and clarification of certain terms and provisions of the Proposed Rule. The SAB's advice and comments on the Proposed Rule and aspects of the supplemental notice are provided in the enclosed report.[1]

The Proposed Rule is intended to strengthen the transparency of EPA regulatory science by providing that, for the science pivotal to its significant regulatory actions, EPA will ensure that the data and models underlying the science are publicly available in a manner sufficient for validation and

[1] Drs. John Graham and Donald van der Vaart indicated that they did not concur with the enclosed report. Their dissenting opinions are included in Appendix A.

analysis. The SAB recognizes the importance of this rule and its purpose, establishing transparency of the influential scientific information used for significant regulations and enhancing public access to scientific data and analytical methods to help ensure scientific integrity, consistency and robust analysis.[2] Strengthening transparency by improving access to data can lead to an increase in the quantity and the quality of evidence that informs important regulatory science and policy decisions. The scientific community is moving toward adopting the precept of sharing accurate data and information to increase credibility, high-quality outcomes and public confidence in science. The SAB supports the adoption of this precept. However, the SAB finds that key considerations that could inform the Proposed Rule are not present in the proposal or presented without analysis and explanation of scope. In addition, certain key terms and implementation issues have not been adequately defined or described. To provide clarity on the procedures for conducting the proposed efforts, the SAB strongly encourages the development of additional policy and/or guidance documents. In addition, the SAB has concerns about the scientific and technical challenges of implementing some requirements of the Proposed Rule. The SAB's major comments and recommendations are as follows:

- The Proposed Rule requires the EPA to clearly identify all studies (or other regulatory science) relied upon when it takes any significant final agency regulatory action and to make all such studies available to the public to the extent practicable. The EPA's Supplemental Notice of Proposed Rulemaking expands the scope of this requirement to include studies relied upon in influential scientific information (i.e., scientific information that will or does have a clear and substantial impact on important public policies or private sector decisions). In some cases, this requirement could be complex and/or impractical because studies could be considered when integrating the evidence but not directly used to determine specific regulatory standards or levels. The lack of specific criteria for what might satisfy the requirement makes it difficult for the SAB to understand the implications. The SAB recommends that the Final Rule describe in greater detail and clarity how the requirement can be met. To effectively implement this requirement, at the minimum, pivotal regulatory science or other regulatory science (as defined in the Proposed Rule), as well as other types of data necessary to make regulatory determinations, should be publicly available with a scientific justification explaining why they were used for regulatory decisions. As stated in the Proposed Rule, EPA should indicate whether an independent peer review of all pivotal regulatory science has been conducted. As discussed below, the proposed rule provides for exceptions to be granted if it is not feasible to implement these requirements. The SAB suggests that the EPA consider establishing an office (or virtual office) on data sharing, and a peer review panel or workgroup to assist EPA in this process.

- The Proposed Rule and the supplemental proposal indicate that when promulgating significant regulatory actions or finalizing influential scientific information, the Agency shall ensure that data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation. EPA's Supplemental Notice of Proposed Rulemaking has indicated that the requirement to make data and models underlying pivotal science available in a manner sufficient for independent validation would apply to all data and models, not just dose-response models. Greater clarity is needed in the definitions of those terms. The SAB recommends that the definitions provided in the Proposed Rule and supplemental proposal be expanded and supported in the context of a guidance document.

[2] One SAB member does not agree with this statement, particularly in the context of international studies and those developed before the acceptance of current standards on science transparency that are discussed in this report

- The Proposed Rule indicates that the Administrator may grant exceptions to the requirements on a case-by-case basis if it is determined that compliance is impracticable because: (1) it is not feasible to ensure that all pivotal regulatory science is publicly available for independent validation in a manner that is: consistent with law; protects privacy, confidentiality and confidential business information; and is sensitive to national and homeland security; or (2) it is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions. The SAB notes that in the supplemental proposal, EPA has provided additional information about exceptions to the requirements. However, the SAB recommends that EPA develop specific criteria for such exceptions as part of the Final Rule. Although it will be difficult to develop criteria for exceptions, outlining such criteria would benefit EPA and help ensure that the principles of transparency outlined in the Proposed Rule are accomplished. Case-by-case exceptions without such criteria may create public concerns about inappropriate exclusion of scientifically important studies. A framework and/or guidance document could also help EPA clarify how current scientific review procedures will be affected by this rule. It might be useful for the EPA to consider recommendations from a scientific advisory committee when making decisions to waive requirements.

- To assess the feasibility of making data and models available in a manner sufficient for independent validation, a number of questions must be answered (such as how to treat studies that are formatted in a manner that makes the data difficult to share, how to move forward if laboratories refuse to collate and release data, how to handle sensitive information such as individual participants' addresses, how to manage international studies, and how to manage conclusions drawn from meta-analysis). The SAB notes that historical data or international datasets may be unavailable or may have been discarded if deemed not necessary to maintain. A possible way to address this problem is to apply rule requirements only to information developed after the effective date of a Final Rule. Experimental considerations (such as the appropriateness of controls, protocols employed, limits of quantification, and other considerations) must be made known to determine whether data are valid. The SAB recommends that the EPA consider these questions and more specifically define "independent validation" in the Final Rule because this definition drives the feasibility of whether the EPA can make data and models available in a manner sufficient for validation.

- The SAB recommends that EPA consider seeking input from experts in library science, data curation management, and data retention to identify best practices and tools to ensure efficiency and utility of data that are made available. There will be costs associated with assessing and disseminating data as required in the Proposed Rule.

- The requirement in the Proposed Rule that "data" be made publicly available is vague and, as a result, can be interpreted in different ways. Extensive work is required, across a diversity of fields, data types and data of different ages, to understand the implications of adopting different definitions of data and more clarity is needed to define the nature of the "data" that are being required. The SAB notes that EPA has defined data in the supplemental proposal. The SAB finds that EPA could benefit from using the term "analysis dataset" as it refers to data that have been collected and processed (e.g., cleaned and transformed) for analysis.

- As stated in the Proposed Rule, when the Agency is making data or models publicly available, it shall do so consistent with the law to protect privacy and confidentiality. Therefore, this regulation should build on techniques and practices to protect the confidentiality of human data when data and models underlying pivotal regulatory science are made available to the public. Some individual data used in epidemiological studies are held by federal agencies such as the Centers for Disease Control

and Prevention (CDC) or the Department of Health and Human Services (Medicare data), while other data have been developed by state, local or tribal governments, academic institutions or private organizations, among others. Some federal agencies have efficiently developed methods for making data available to the public (e.g., Census Bureau, CDC). Currently, no comparable system exists for datasets that are owned by non-federal governments (e.g., states, tribes), and/or owned by private societies/organizations or academic institutions which are themselves protected by strong privacy and confidentiality requirements through their Institutional Review Boards (IRBs). The SAB recommends that EPA collaborate with federal agencies to make individual-level data (i.e., data associated with individuals in a sample) available through the system of Federal Statistical Research Data Centers, which are already widely used by the Census Bureau to allow researchers to gain access to individual data while protecting the data from public dissemination. The SAB also notes that there are techniques and practices to protect sensitive data that have been well-developed by researchers involved in studies with human subjects. The Proposed Rule should clearly address the issue of obtaining public access to datasets while maintaining the privacy of the study participants and confidentiality of the data. If this issue is not clearly addressed, there is a risk of entirely excluding datasets containing personally identifiable information from being considered as pivotal regulatory science.

- If the EPA wants to encourage reanalysis to validate datasets that are critically important for regulation, the Agency should consider providing funds to conduct such reanalysis. A model for this was established by the Health Effects Institute (HEI) in its 2000 reanalysis of datasets from the Six Cities Study and the American Cancer Society.

- The Proposed Rule requires the EPA to describe and document any assumptions and methods that pertain to the use of data and models underlying pivotal regulatory science and to describe variability and uncertainty. It is unlikely that uniform standards will be used across laboratories to report this information; therefore, the SAB strongly suggests that, before the implementation of the Final Rule, the EPA develop a guidance document pertaining to documentation of assumptions, methods, variability, and the definition of data and uncertainty.

The SAB appreciates the opportunity to provide the EPA with advice and comment on the Proposed Rule. We look forward to receiving the Agency's response.

Sincerely,

/s/

Dr. Michael Honeycutt, Chair
Science Advisory Board

Enclosure

NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board (SAB), a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names of commercial products constitute a recommendation for use. Reports of the SAB are posted on the EPA Web site at http://www.epa.gov/sab.

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1. EXECUTIVE SUMMARY

As part of its statutory duties, the EPA Science Advisory Board (SAB) may provide advice and comment on the scientific and technical basis of certain planned EPA actions. The Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA) requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations provided to any other federal agency for formal review and comment, together with relevant scientific and technical information on which the proposed action is based. The SAB may then provide advice and comments on the scientific and technical basis of the proposed action.

At its May 31, 2018 public meeting, the Chartered SAB identified the proposed rule titled *Strengthening Transparency in Regulatory Science* (Proposed Rule) as a planned action that merited review. In April 2019, the SAB Work Group on Planned Actions for SAB Consideration of the Underlying Science recommended that the SAB review the Proposed Rule and at its public meeting on June 5-6, 2019, the SAB elected to review the scientific and technical basis of the Proposed Rule. Subsequent to the June meeting, a work group of chartered SAB members was formed to carry out the review. Members of this work group then took the lead in SAB deliberations on this topic at a public teleconference held on January 21, 2020. On March 3, 2020, EPA announced a Supplemental Notice of Proposed Rulemaking (SNPRM),[3] which contains additional information and clarification of certain terms and provisions of the Proposed Rule. The SAB's advice and comments on the Proposed Rule and aspects of the supplemental notice are provided in this report.[4]

The Proposed Rule is intended to strengthen the transparency of EPA regulatory science by providing that, for the science pivotal to its significant regulatory actions, EPA will ensure that the data and models underlying the science are publicly available in a manner sufficient for validation and analysis. The SAB recognizes the importance of this rule. It can enhance public access to scientific data and analytical methods, and help ensure scientific integrity, consistency and robust analysis.[5] Strengthening transparency by improving access to data can lead to an increase in both the quantity and the quality of evidence that informs important regulatory science and policy decisions. The scientific community is moving toward adopting the precept of sharing accurate data and information to foster credibility, high-quality outcomes and public confidence in science. The SAB supports the adoption of this precept.

The SAB finds, however, that key considerations that could inform the Proposed Rule are not present in the proposal, or presented without analysis, and certain key terms and implementation issues have not been adequately defined or described. In addition, the SAB has concerns about the scientific and technical challenges and feasibility of implementing some requirements of the

[3] Strengthening Transparency in Regulatory Science; Supplemental Notice of Proposed Rulemaking, 25 Federal Register (18 March, 2020), pp. 15396-15406.
[Available at: https://www.federalregister.gov/documents/2020/03/18/2020-05012/strengthening-transparency-in-regulatory-science]

[4] Drs. John Graham and Donald van der Vaart indicated that they do not concur with this report. Their dissenting opinions are included in Appendix A.

[5] One SAB member does not agree with this statement, particularly in the context of international studies and those developed before the acceptance of current standards on science transparency that are discussed in this report.

Proposed Rule. Given the relatively skeletal nature of the Proposed Rule, it is not possible to define the implications of the rule with confidence. To ensure that the rule is evidence-based EPA must provide greater clarity regarding details of the rule and how it will be implemented, as well as example analyses of how it would be deployed. The development of additional policy and/or guidance documents is strongly recommended to provide clarity on the procedures for conducting the proposed efforts.

The Proposed Rule requires the EPA to clearly identify all studies (or other regulatory science) relied upon when it takes any significant final agency regulatory action and to make all such studies available to the public to the extent practicable. The EPA's Supplemental Notice of Proposed Rulemaking expands the scope of this requirement to include studies relied upon in influential scientific information (i.e., scientific information that will or does have a clear and substantial impact on important public policies or private sector decisions). In some cases, this requirement could be complex and/or impractical because studies could be used and considered when integrating evidence but not directly used to determine specific regulatory standards or levels. The lack of specific criteria for what might satisfy the requirement makes it difficult for the SAB to understand the implications. The SAB recommends that the Final Rule describe in greater detail and clarity how the requirement can be met. To effectively implement this requirement, at the minimum, pivotal regulatory science and regulatory science (as defined in the Proposed Rule), as well as other types of data necessary to make regulatory determinations, should be publicly available with a scientific justification explaining why they were used for regulatory decisions. As stated in the Proposed Rule, EPA should indicate whether an independent peer review of all pivotal regulatory science has been conducted. As discussed below, the proposed rule provides for exceptions to be granted if it is not feasible to implement these requirements.

If the intent of the rule is to identify and make available the pivotal regulatory science that was relied upon, scientific and technical challenges of implementing this requirement will consist of: (1) having EPA be explicit about which studies are pivotal to the recommended regulatory action, and (2) making the data and models for the underlying pivotal studies publicly available. Given the lack of clarity in the Proposed Rule, it is difficult to understand how this regulatory action could be accomplished in a standardized and consistent manner. The Proposed Rule and supplemental proposal acknowledge the importance of protecting personally identifiable information (PII) and confidential business information (CBI). This SAB report contains additional suggestions regarding the protection of PII and CBI. The EPA must make certain that PII and CBI are not available to persons and groups who are not approved to have access to this information. Without adequate protection, industry data generated by one company can be used by other companies to fulfill regulatory requirements in other geographies. It would be beneficial for the EPA to develop specific policies to address: the protection of PII and CBI, exceptions that would be appropriate where PII and CBI cannot be released, and whether data compensation should be considered. The identification and release of individual data to the public in epidemiological studies that arise from small datasets or targeted geographic areas is problematic, but there are approaches that have been used to protect PII, (e.g., conducting independent analysis by a third party such as Health Effects Institute). However, the lack of criteria for what data might satisfy the requirements of the Proposed Rule makes it difficult to understand the implications for protection of PII. The SAB recommends that the EPA develop specific definitions of terms and methods for meeting the requirements.

The Proposed Rule should build on techniques and practices to protect human data when data and models underlying pivotal regulatory science are made available to the public. Some individual data (i.e., data associated with individuals in a sample) used in epidemiological studies are held by federal agencies such as the Centers for Disease Control and Prevention or the Department of Health and Human Services (Medicare data), while other data have been developed by state, local or tribal governments, academic institutions or private organizations, among others. Some federal agencies have efficiently developed methods for making data available to the public (e.g., Census Bureau, CDC). Currently, no comparable system exists for datasets that are owned by non-federal governments (e.g., states, tribes), and/or owned by private societies/organizations or academic institutions, which are themselves protected by strong privacy and confidentiality requirements through their Institutional Review Boards (IRBs).

It seems reasonable that the standards applied by the EPA to protect sensitive data and copyrighted or confidential business information should be the same as the standards applied by editors of reputable scientific journals (e.g., guidance from the International Committee of Medical Journal Editors). Techniques and practices such as microaggregation to protect sensitive data have been developed by researchers involved in studies with human subjects, but such an approach may make the data unsuitable for modeling. The SAB recommends that EPA collaborate with other federal agencies to make individual-level data available through the system of Federal Statistical Research Data Centers, which are already widely used by the Census Bureau to allow researchers to gain access to individual data while protecting the data from public dissemination. The SAB also notes that there are techniques and practices to protect sensitive data that have been well-developed by researchers involved in studies with human subjects. The proposed regulation should clearly address the issue of obtaining public access to datasets while maintaining the privacy of the participants and confidentiality of the data, because without such access, sensitive data and confidential business information could be excluded entirely from consideration as pivotal regulatory science.

The Proposed Rule states that when promulgating significant regulatory actions, the Agency shall ensure that data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation. The SAB finds that greater clarity is needed in definitions of “data and models” and “pivotal regulatory science.” EPA’s Supplemental Notice of Proposed Rulemaking has indicated that the requirement to make data and models underlying pivotal science available in a manner sufficient for independent validation would apply to all data and models, not just dose-response models. The definitions provided in the Proposed Rule are not adequate and may be better supported in the context of a guidance document that includes realistic examples of the types of data and models of interest and the requirements for reporting this information. The SAB notes that this regulation could benefit from use of the term “analysis dataset” to define data that should be made publicly available.[6] This term refers to data that have been collected and processed (e.g., cleaned and transformed) for analysis. A technical issue to be considered is how to separate datasets and models that were the basis of calculations used to

[6] The SAB notes that protecting privacy and confidentiality must be taken into consideration when data and models underlying pivotal regulatory science are made available to the public. Requirements for protection of privacy have been established under the Health Insurance Portability and Accountability Act (HIPAA). Although the proposed Rule suggests that privacy and confidentiality can be addressed through anonymization or de-identification, even de-identified datasets present risks of re-identification (Rocher et al. 2019).

drive the quantitative assessment from ancillary data and models that were part of the weight of evidence.

The Proposed Rule indicates that the Administrator may grant exceptions to the requirements of the Proposed Rule on a case-by-case basis if it is determined that compliance is impracticable because: (1) it is not feasible to ensure that all pivotal regulatory science is publicly available for independent validation in a manner that is consistent with law; protects privacy, confidentiality, and confidential business information; and is sensitive to national and homeland security; or (2) it is not feasible to conduct independent peer review of all pivotal regulatory science used to justify regulatory decisions. The SAB recommends that the EPA develop specific criteria for such exceptions as part of the Final Rule. Although it will be difficult to develop criteria for exceptions, outlining such criteria would benefit EPA and help ensure that the principles of transparency outlined in the Proposed Rule are accomplished. Case-by-case exceptions without criteria may create public concerns about inappropriate exclusion of scientifically important studies. A framework and/or guidance document could also help EPA clarify how the rule will affect current scientific review procedures. It might be useful for the EPA to consider recommendations from a scientific and advisory committee when making waiver decisions.

In order to assess the feasibility of making data and models available in a manner sufficient for independent validation, some critical elements should be considered (e.g., how to treat studies that are formatted in a manner that make the data difficult to share, how to move forward if laboratories refuse to collate and release data, how to handle sensitive information such as individual participants' addresses, how to manage international studies, and how to manage conclusions drawn from meta-analysis). Experimental considerations must be made known to determine whether data are valid (e.g., the appropriateness of controls, protocols employed, limits of quantification). Assessing the validity of epidemiological studies for the purposes of the Proposed Rule could pose scientific and technical challenges. Important issues to be addressed include understanding bias, confounding factors, measurement errors and exposure characterization. All these factors play a role in defining what would be appropriate for data access and study validation purposes. The SAB encourages EPA to consider these questions and define "independent validation" in the Proposed Rule because this definition drives the feasibility of whether the EPA can make data and models available for validation. The SAB recommends that EPA develop a guidance document to clarify these issues and how the requirement would be managed.

The requirement in the Proposed Rule that "data" be made publicly available is vague and, as a result, can be interpreted in different ways. If "data" includes all machine output or individual data sheets on study participants associated with analysis the requirement would create demands on researchers that could impact the science-based decision-making process. The Proposed Rule should follow evolving norms developed by the scientific community as well as federal agencies (e.g., National Science Foundation, National Institutes of Health, National Oceanic and Atmospheric Administration, Department of Energy). The EPA should consider seeking input from experts in library science, data curation management and data retention to identify best practices and tools to ensure efficiency and utility of data that are made available.

There will be costs associated with assessing and disseminating data as required by the Proposed Rule. Funding agencies may have different time limits for retaining data. Historical datasets might not be available at the level of detail needed for recalculation. Some of the data or

computational methods may have been discarded if they were deemed not necessary to maintain. The SAB suggests that the EPA consider establishing an office (or virtual office) on data sharing, and a peer review panel or workgroup to assist EPA in this process (e.g., American Society for Testing and Materials (ASTM) and the International Organization for Standardization (ISO) have workgroups and approaches to establish valuable consensus standards). This group could identify: standard data formats (data templates); how to report methods/procedures used; uncertainty; and when and how to implement greater data protections for PII/CBI. The SAB notes that processing and documenting data and models developed prior to the effective date of the rule will pose challenges. A possible way to address this is to apply rule requirements only to information developed after the effective date of a Final Rule. Standards on transparency are evolving, and modern expectations do not apply to studies completed 10 or 20 years ago. It is reasonable to apply modern standards of transparency and public availability to current and future studies, but it will not always be possible to apply these same standards retrospectively.

It is difficult to develop a definition of "data" that would meet EPA's objectives in proposing this rule. The definitions of data would likely differ based on the available dataset and the types of data accumulated. However, the SAB recommends the development of definitions to clarify the requirement to make data available. "Data" should not be confused with personally identifiable data. Extensive work would be required, across a diversity of fields, data types and data of different ages, to understand the implications of adopting different definitions of data. More clarity is also needed to define the nature of the "data" that must be publicly available. As previously noted, this regulation could benefit from using the term "analysis dataset" to define data that must be made publicly available.

The Proposed Rule requires the EPA to describe and document any assumptions and methods that pertain to the use of data and models underlying pivotal regulatory science and to describe variability and uncertainty. High quality scientific studies identify the assumptions used in models, methods used, the variability of the replications, and any other confounders that add to the uncertainty of the final dataset, so these are not unusual or inappropriate factors to address. However, certain scientific and technical challenges must be surmounted. One would anticipate variability in the reporting across laboratories; therefore, the SAB strongly suggests that, before the implementation of the Final Rule, the EPA develop a guidance document pertaining to assumptions, methods, variability, the definition of data and uncertainty.

2. INTRODUCTION

As part of its statutory duties, the EPA Science Advisory Board (SAB) may provide advice and comment on the scientific and technical basis of certain planned EPA actions. The Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA) requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations provided to any other federal agency for formal review and comment, together with relevant scientific and technical information on which the proposed action is based. The SAB may then provide advice and comments on the scientific and technical basis of the proposed action.

At its May 31, 2018 public meeting, the chartered SAB identified the Proposed Rule titled *Strengthening Transparency in Regulatory Science* as a planned action that merited review. In April 2019, the SAB Work Group on Planned Actions for SAB Consideration of the Underlying Science recommended that the SAB review the Proposed Rule and at its public meeting on June 5-6, 2019, the SAB elected to review the scientific and technical basis of the Proposed Rule. Subsequent to the June meeting, a work group of chartered SAB members was formed to carry out the review. Members of this work group then took the lead in SAB deliberations on this topic at a public teleconference held on January 21, 2020. On March 3, 2020, EPA announced a Supplemental Notice of Proposed Rulemaking (SNPRM),[7] which contains additional information and clarification of certain terms and provisions of the Proposed Rule. This report provides the SAB findings and recommendations related to the Proposed Rule and aspects of the supplemental notice.[8]

[7] Strengthening Transparency in Regulatory Science; Supplemental Notice of Proposed Rulemaking, 25 Federal Register (18 March, 2020), pp. 15396-15406.
[Available at: https://www.federalregister.gov/documents/2020/03/18/2020-05012/strengthening-transparency-in-regulatory-science]

[8] Drs. John Graham and Donald van der Vaart indicated that they do not concur with this report. Their dissenting opinions are included in Appendix A.

3. SAB ADVICE AND COMMENT ON THE PROPOSED RULE

The SAB has reviewed EPA's proposed rule titled *Strengthening Transparency in Regulatory Science* (Proposed Rule) and provides the following comments on the scientific and technical basis of the proposed action. The SAB also provides recommendations to strengthen the science informing the Proposed Rule.

3.1. General Comments

The Proposed Rule is intended to strengthen the transparency of EPA regulatory science by providing that, for the science pivotal to significant regulatory actions, EPA will ensure that the data and models underlying the science are publicly available in a manner sufficient for validation and analysis. The SAB recognizes the importance of this rule and its purpose, establishing transparency of the scientific information used for significant regulations and enhancing public access to scientific data and analytic methods to help ensure scientific integrity, consistency and robust analysis.[9] Strengthening transparency by improving access to data can lead to an increase in both the quantity and the quality of evidence that informs important regulatory science and policy decisions. The scientific community is moving toward adopting the precept of sharing accurate data and information to increase credibility, high-quality outcomes and public confidence in science. The SAB supports the adoption of this precept.

The SAB recognizes that the long-term trend in most scientific fields is for authors to supply public access to data and analytic methods after scientific findings are published. Such transparency helps to ensure scientific integrity and facilitate robust analysis, as well as allow supplementary lines of knowledge to be developed from the same data. Enhancing the transparency and validity of the scientific information relied upon by EPA and increasing public access to data are worthy goals. However, the SAB finds that key considerations are not present in the Proposed Rule or presented without analysis and explanation of scope. In addition, certain key terms and implementation issues have not been adequately defined or described. The development of additional policy and/or guidance documents is strongly encouraged to provide clarity on the procedures for conducting the proposed efforts. The SAB also has concerns about the scientific and technical challenges of implementing some requirements of the Proposed Rule. The SAB has provided recommendations to facilitate implementation of the Proposed Rule.

3.2. Requirement to Identify All Studies and Regulatory Science Supporting Final Agency Actions

The Proposed Rule requires the EPA to clearly identify all studies (or other regulatory science) relied upon when it takes any significant final agency regulatory action and make such studies available to the public to the extent practicable. The EPA's Supplemental Notice of Proposed Rulemaking expands the scope of this requirement to include studies relied upon in influential scientific information (i.e., scientific information that will or does have a clear and substantial impact on important public policies or private sector decisions). This requirement could be complex and/or impractical because some studies could be considered when integrating evidence but not directly used to determine specific regulatory standards or levels.

[9] One SAB member does not agree with this statement, particularly in the context of international studies and those developed before the acceptance of current standards on science transparency that are discussed in this report.

The lack of criteria for satisfying the requirement to "make all such studies available to the public to the extent practicable" makes it difficult to understand the implications of the requirement. Criteria are needed to define the requirement. A question to be answered is whether making the scientific papers reporting these studies available without charge makes the studies "available," or whether all data from every measurement taken as part of the study need to be available to anyone to analyze. At one end of this range of interpretation the requirement is easily implementable. On the other end of the spectrum, meeting the requirement would be enormously expensive and time consuming at best and could be expected to result in the exclusion of much of the scientific literature from consideration (the machine data may no longer be available and/or the researchers may no longer be alive or in a position to assemble the data). The net effect could be minimal or complex.

The SAB recommends that the Final Rule describe in greater detail and clarity how the requirement can be met. To effectively implement the requirement, at the minimum, pivotal regulatory science and regulatory science (as defined in the Proposed Rule), as well as other types of data necessary to make regulatory determinations, should be publicly available with a scientific justification explaining why they were used for regulatory decisions. As stated in the Proposed Rule, EPA should indicate whether an independent peer review of all pivotal regulatory science has been conducted. As discussed below, the proposed rule provides for exceptions to be granted if it is not feasible to implement these requirements.

Scientific and technical challenges of making all studies supporting regulatory actions available to the public

The SAB finds that requiring the identification of all studies and regulatory science supporting regulatory actions and making them available for reanalysis will be a complex process.[10] As previously discussed, identifying and making "pivotal science data or studies" available could present challenges if some studies were considered in the regulatory decisions but were not used to determine the point of departure (POD) or reference dose (RfD) or other regulatory/technical level. It is not clear how much information and which studies should be included in the requirement to identify and make studies available. This should be clarified in the Proposed Rule. As further discussed in Sections 3.2 and 3.3 of this report, if the intent of the rule is to make available for reanalysis "all underlying pivotal science supporting influential scientific information and/or pivotal regulatory science" that contributed to the ultimate regulatory decision, then practical procedures must be established for an independent validation.

EPA must also make certain that personally identifiable information (PII) and confidential business information (CBI) are not available to persons/groups not properly vetted, approved, and trusted by those owning the CBI information. Without adequate protection, industry data generated by one company can be used by other companies to fulfill regulatory requirements in other geographies. It would be beneficial for the EPA to develop some specific policies related to: the protection of PII and CBI, exceptions that would be appropriate where CBI cannot be released, and whether data compensation should be considered. When PII and CBI data or methods are made available, "the public" receiving the information should be a small group of

[10] The level of complexity will depend upon the studies and information that must be identified and made available for reanalysis.

people who have provided assurance that they will keep such information confidential and protected. EPA could consider developing tiers of public access that may provide a base level of information (e.g., a robust summary or final study report which is devoid of confidential protected information) for the general user or member of the public and then restrict the availability of additional information to a smaller group when access to confidential or copyrighted information is warranted. In matters of public health, it is common to require disclosure to a trusted third party. In the case of environmental epidemiological studies, microaggregation of data can be used to protect personal identity. The SAB notes that the supplemental proposal indicates the Agency will only use studies containing CBI and PII if there is tiered access to the data or if the data can be sufficiently de-identified.

It may not be practical for EPA to make all studies or other regulatory science used in a final regulatory action available to the public. Many studies are included as part of a regulatory evaluation, but some studies or data may not drive the final regulatory decision (e.g., because of insufficient sample size or doses that are too high). The EPA could consider producing a list of study data considered in an evaluation and then strive to provide data for critical studies driving regulatory limits (e.g., "pivotal studies"). The SAB notes that the Proposed Rule could benefit from use of the term "analysis dataset" to define data that should be made publicly available.[11] This term refers to data that have been collected and processed (e.g., cleaned and transformed) for analysis. In this way, the public could understand which studies/data were considered and used without expending the resources to gather and disseminate all available data. The level of detail required to allow the public to transparently reach the same conclusion(s) as the Agency will differ among individuals who seek the data. Some people may wish to verify that the EPA has selected the right "pivotal studies." However, a more expansive scope would increase the reporting burden in a way that may make the Proposed Rule untenable.

The scientific and technical challenges of making pivotal studies supporting regulatory actions available to the public consist of: (1) having EPA be explicit about which studies are pivotal to the recommended regulatory action (e.g., using a decision and risk analysis framework that explicitly derives recommended actions from study results, and thus enables the roles of studies in the regulatory actions to be precisely identified); and (2) making the data and models for the underlying pivotal studies publicly available. The first step may be relatively technically straightforward to implement if standard decision and risk analysis frameworks are used to derive policy recommendations from study results. However, there are a number of emerging technologies (e.g., use of transcriptomics data) that raise new challenges, including dealing with "big data" (i.e., extremely large datasets to be analyzed computationally). It may also be very challenging to identify pivotal studies if holistic judgments and weight-of-evidence frameworks are used. Likewise, the second step, making available the data and models underlying pivotal scientific studies, is also technically straightforward when the pivotal studies already provide the analysis dataset and document the models used to analyze it and to reach their conclusions.[12]

[11] The SAB notes that protecting privacy and confidentiality must be taken into consideration when data and models underlying pivotal regulatory science are made available to the public. Requirements for protection of privacy have been established under the Health Insurance Portability and Accountability Act (HIPAA). Although the proposed Rule suggests that privacy and confidentiality can be addressed through anonymization or de-identification, even de-identified datasets present risks of re-identification (Rocher et al. 2019).

[12] Some SAB members are concerned that the Proposed Rule contains contradictory statements about whether its effect would be to prohibit EPA from considering studies for which underlying data cannot be made publicly available. Major public health protections, like the National Ambient Air Quality Standards (NAAQS) for ozone and

Typically, an analysis dataset lists values of exposure, response, and covariate variables and uses multiple imputation and related methods for missing data and confidentiality (Reiter and Raghunathan, 2007). Such datasets have already been made publicly available in studies such as NHANES III (National Center for Health Data Statistics 2019). Publishing such analysis datasets and the models used to analyze them to produce conclusions that are pivotal to regulatory action seems to be an appropriate scope of coverage for the stated goal, i.e., "to increase transparency in the preparation, identification, and use of science in policymaking." [13]

It may not be feasible to identify and make available data in epidemiological studies that arise from small datasets or targeted geographic areas, especially if the Informed Consent Form indicated that only the particular researchers who conducted the study would have access to the information and data. If the participants agreed to grant only a select group of researchers access to their personal information, then that consideration should be respected, and such information should not be supplied to additional people for validation. It would probably be impractical, to go back to the participants and request their approval to provide additional people access to personal information. Therefore, the identification of "analysis dataset" when referring to data (i.e., analysis dataset is data that have been collected and processed, cleaned and transformed for analysis) could be useful in this regard as it does not contain personal identifiers.

Some of the major cohort studies, such as the Women's Health Initiative (WHI) (National Heart, Lung, and Blood Institute, 2020) or the Atherosclerosis Risk in Communities (ARIC) Study (ARIC Investigators, 1989), require researchers to write a manuscript proposal, study design or protocol – in effect, a document describing the study they intend to conduct, including data that are required and the rationale behind the study (Prentice et al., 1998; ARIC Investigators, 1989). The proposal is reviewed by a committee and, in most cases, is either approved without modification or returned to the investigators to address specific issues. It is possible that the EPA could work with holders of private datasets to develop such study designs or protocols or a similar system of broader applicability. That approach would provide a mechanism for interested researchers to access datasets for reanalysis under appropriate controls where relevant for EPA regulations. The SAB encourages the development of data center protocols to address procedures regarding data availability for independent validation.

3.3. Requirement to Ensure that Data and Models Underlying Pivotal Regulatory Science are Publicly Available in a Manner Sufficient for Independent Validation

The Proposed Rule states that when promulgating significant regulatory decisions, the Agency shall ensure that data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation. The supplemental proposal (Revised §30.3) has indicated that this requirement would apply to "data and models, underlying pivotal science supporting influential scientific information and/or underlying pivotal regulatory science," not

oxides of nitrogen, drinking water standards for arsenic, and Toxic Substances Control Act (TSCA) standards for formaldehyde emissions in composite wood rely on studies that include confidential data.

[13] One SAB member suggests that, to accomplish this, the EPA should not fund new research unless researchers file a research protocol, provide analysis datasets to EPA and the public, and provide analysis code. The SAB member also suggests that previous research should not be considered to support regulatory actions unless researchers provide sharable datasets, analyze them, provide analysis code, and file these materials with the EPA. The SAB notes, however, that institutional review boards at host universities may not agree with the requirement that data be deposited with EPA as a condition of funding.

just dose response data. The SAB recommends that the EPA clarify the definitions of "data and models" and "pivotal regulatory science." It would be useful to develop a guidance document that includes examples of the types of data and models of interest and requirements for reporting this information. It would be particularly useful to clarify specific requirements for reporting information from animal toxicity and/or environmental epidemiology studies. The Proposed Rule indicates that pivotal regulatory science refers to studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions. Although this definition is adequate for some practical purposes, the EPA should clarify whether this includes all the hazard characterization and dose response models that the Agency evaluated and captured in its analysis or only the final model ultimately selected.[14] As previously discussed, data might be defined as the "analysis dataset" (i.e., listing values of causally relevant exposure, response, and covariate variables, and uses of multiple imputation and related methods for representing missing data and confidential data). Dose-response model might be defined as "the model or algorithm used to calculate conditional probability of a stated health response caused by stated exposures together with the values of any other direct causes of the response (e.g., stated levels of causally relevant covariates such as co-exposures and co-morbidities)." The SAB notes that the Final Rule should define and clarify when the requirements are applicable to animal toxicity studies or environmental epidemiology studies.

When defining these terms, the following questions should be considered with regard to dose-response data. Are there any requirements for the number of dose levels or dose spacing? Does this mean that single dose studies will be excluded? If not, under what circumstances would these studies be included? What types of models are "in scope?" What type of information is needed for each model type – animal toxicity or epidemiological data? Is the goal to provide equations, allowing the public to replicate the math or to provide models with assumptions that the public can evaluate in detail? Are there standard approaches for modeling dose-response relationships (benchmark dose? other?) If so, under what conditions are different dose-response approaches implemented? Can a framework be prepared to outline the EPA's approach? To make the Proposed Rule more practical, pivotal regulatory science could be defined as the study (or studies if necessary) on which the regulatory limit is based. Ideally, the EPA should provide a brief explanation of why the selected study is the pivotal study and why other studies were not selected.

Protecting privacy and confidentiality

As previously discussed, protecting privacy and confidentiality must be taken into consideration when data and models underlying pivotal regulatory science are made available to the public. Although the Proposed Rule suggests that privacy and confidentiality issues can be addressed through anonymization or de-identification, this is not always the case. The U.S. Office of Management and Budget (OMB, 2013), Health Effects Institute[15], National Academies of

[14] A technical issue to be considered when defining models and data is how to separate datasets and models that were the actual basis of the calculations used to drive the quantitative assessment, e.g., point of departure (POD) or reference dose (RfD), from additional datasets and models that may have been ancillary but part of the weight of evidence used in the regulatory action. Reasons for the choice of the primary datasets and models for the quantitative assessment and reasons for placing the other options in the weight of evidence (WOE) category should be made available.

[15] Letter from Daniel S. Greenbaum, Health Effects Institute, to Lek Kadeli, Environmental Protection Agency (Aug. 27, 2013) ("noting increasingly granular data used in health studies and stating that "these characteristics -

Science (NRC, 2005), and independent experts (Rothstein, 2010; Commission on Evidence-Based Policy Making, 2017; Rocher et al., 2019) have all found that even de-identified datasets present significant risks of re-identification given modern techniques for combining these datasets with other sources of individual information (also known as a "mosaic effect"). Where risk of personal identification is high, the SAB recommends using approaches such as independent analysis by a third party, e.g., Health Effects Institute (HEI).

Scientific and technical challenges and feasibility of making data and models publicly available in a manner sufficient for independent validation

The SAB notes that a number of specific scientific and technical challenges must be addressed, and questions answered, in order to make data and models available in a manner sufficient for independent validation. There are experimental considerations that must be known in order to determine whether experimental data are valid (e.g., appropriate controls, protocols employed, where data fall within the standard curve of the target analyte, limit of quantification, dynamic range of the instrument, calibration of instruments, condition of experimental animals, blinding of reading of slides or behavioral observations, stability of samples, qualifications and approach of researchers obtaining epidemiological data). Also, there is a need to know what information was used in models (e.g., whether all data points were used, how confounders were handled in epidemiological studies, what statistical models were used, what predictive models were used, the fit of the model to the data). Independent validation requires sufficient information about how the original data were collected and analyzed in order to know whether the validation procedures are likely to yield the same result as the original calculations.

Therefore, it would be useful for the EPA to specifically define "independent validation." EPA's supplemental proposal indicates that independent validation means the reanalysis of study data by subject matter experts who have not contributed to the development of the study to demonstrate that the same analytic results reported in the study are capable of being substantially reproduced. However, the specific definition of independent validation drives the feasibility of whether EPA can make data and models available for independent validation. For example, the EPA should consider the following questions: How much information is sufficient for independent validation? Will this information consist of equations where reviewers can verify the math, more detailed models where assumptions and limitations are described, or code to allow the public to evaluate and run the models if desired? Is this information simply the dose-response data for the endpoint of concern driving a regulatory limit, or is it availability of all data from a pivotal study to allow reviewers to examine the potential contributions of other variables on the primary endpoint of concern? Endpoint data are seldom evaluated in isolation so providing sufficient study information to allow an independent assessment seems important to meet the goals of the Proposed Rule. For example, an effect on pup body weights in a toxicology study should be examined with knowledge of maternal gestational body weight gains, litter size, food consumption, maternal/litter clinical signs, etc. Sample size and variability also play a key role in data interpretation. The SAB notes that EPA Data Quality Guidelines include definitions of replication and validation; this information must be included in the "analysis dataset" with guidance on how to read/interpret it.

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which have in general enhanced the quality and the sensitivity of the studies - increase the difficulty of providing a fully "de-identified" dataset while also enabling a different investigator to conduct a full replication and sensitivity analysis of the original study results.")

It may be beneficial for EPA to develop a guidance document with case studies based on past risk assessments to clarify some scenarios and how the requirement to make data and models publicly available in a manner sufficient for independent validation would be managed (i.e., what is 'in scope' vs. 'out of scope' and rationale). A guidance document may offer clarity on the implementation of this rule. The SAB finds that the following specific questions should be answered or addressed in a post-rule guidance document in order to assess the technical feasibility of making data and models available in a manner sufficient for independent validation.

1. Good laboratory practice (GLP) studies include full disclosure of study data, statistics, instrument calibration, positive control data, etc. Would the EPA make all of these data available to the public for any study judged to be "pivotal?" Would this include GLP audit findings? Will any information in the study be judged by EPA to be CBI?

2. With respect to non-GLP/investigational studies, laboratories may not have data formatted in a manner that makes these data easily shared with the public. How will EPA manage this, particularly when several years may elapse between conduct of a study and its designation as a "pivotal study?"

3. How will the EPA manage and release laboratory data for public review? Will these data be used in risk assessment? Approaches need to be developed to avoid potential bias in risk assessments or regulatory decision-making.

4. How will the EPA manage international studies where there is no requirement for laboratories to provide data to EPA? EPA may have little to no leverage in these situations. Again, the inability to use "pivotal studies" from other geographies could bias risk assessment decisions.

5. How will the EPA manage conclusions drawn from a meta-analysis? Do all studies included in the analysis become "pivotal" studies? This could markedly increase the number of datasets that must be publicly available.

6. How will the EPA justify identification of a "pivotal study" and dose-response without clarifying why other studies were not pivotal? This will require transparent evaluation and reporting of data quality/reliability for available studies that allows reviewers to understand EPA's selection of the "pivotal" study.

7. Some data and models may rely on proprietary software that may not be readily accessible or available and scientists may need to develop their own proprietary code, while other software may be accessible but require considerable data storage or download that may limit utility and availability. How will these models be validated?

Assessing the validity of epidemiological studies

The SAB finds that assessing the validity of epidemiological studies for the purposes of the Proposed Rule poses particular scientific and technical challenges. In general, for the purposes of the Proposed Rule, validation should be defined to include both internal validity and external validity, in the senses defined by Campbell and Stanley (1963). Issues to be addressed include

understanding bias, confounding factors, measurement errors and exposure characterization. All of these factors will play a role in defining what would be appropriate for access and validation purposes. Specifically, one would need the following information: how measurements were taken; how confounders were assessed and dealt with; the institutional review board (IRB) application and subsequent approvals or concerns; the Informed Consent Form (or assent process for children capable of providing assent) or the consent of parents or guardians for information collection on children; the qualifications of the researchers obtaining personal or health information and the consistency of multiple researchers for collection of PII; how truncated datasets for longitudinal studies were handled when participants dropped out of the study or missed sampling times; how environmental samples or human blood samples were taken, handled, stored and analyzed; criteria for how any data points were deemed outliers and eliminated from the dataset; how participants were selected and what the selection/exclusion criteria were. As previously discussed, to address some of these issues, the SAB recommends using approaches such as conducting independent analysis by a third party, e.g., Health Effects Institute (HEI), where risk of personal identification is high, and/or adopting the term analysis datasets as described below.

Challenges and costs of processing and documenting of data prior to public release, maintenance and administration of datasets so they are publicly available, and handling historical datasets

There will be technical, scientific and resource challenges associated with assessing and disseminating data as required by the Proposed Rule. Costs of processing and documenting data will be difficult to assess in advance until EPA has developed a system for dealing with the requirements of the rule. However, the SAB notes that the Agency should consider seeking input from experts in library science, data curation management and data retention to identify best practices and tools to ensure efficiency and utility of data that are made available.

Obtaining data in a useable format with adequate documentation may be difficult. Funding agencies may have different time limits for retaining data. It is likely that not all data will be in a format suitable for public data sharing. Data problems may include: non-traditional data formats, PII, CBI, and inadequate documentation of data or methods. The SAB notes that there may be solutions for some of these data issues, but not for others. Historical datasets might not be available at the level of detail needed for recalculation. Some of the data or computational methods may have been discarded if they were deemed not necessary to maintain. IRB applications usually indicate when individual records can be discarded.

The people or groups processing and handling the data (EPA staff or independent non-EPA consultants) would need to be identified, their credentials and any conflicts of interest with the particular case identified, and documentation secured that they will not reveal confidential information without appropriate permission from the owners of the CBI or PII. The processing might include ways to strip some of the PII of potential identifying information or aggregating the information if these methods would still allow for the validation to be performed. Similarly, the people or groups who would maintain the datasets and provide them to independent public people or groups for validation processes would need to be identified and provide assurance that the data would be maintained as confidential PII or CBI and only released to authorized people or groups. A mechanism would need to be developed for public requests for data access and for approval or disapproval of the requests.

The SAB suggests that EPA consider establishing an office (or virtual office) on data sharing and a peer review panel or workgroup to assist EPA in this process. For example, the American Society for Testing and Materials (ASTM) and the International Organization for Standardization (ISO) have workgroups and approaches to establish valuable consensus standards. This group could provide advice on: standard data formats (data templates), how to report methods/procedures used, uncertainty, when and how to implement greater data protections for PII/CBI, etc. It would be beneficial to build experience and expertise in a group charged to meet this goal. This office could work directly with laboratories and researchers to provide the necessary information in a "user friendly" format. This office also could build and manage data archives and pursue critical historical datasets if deemed important. There will be costs associated with the establishment of such an office as well as researchers' time to collate data and work with EPA to make these data publicly available. It is unclear how the EPA will manage these additional costs. In the future, it might be possible for EPA to develop a reporting framework for laboratories so that study data are collected in a format that requires less rework if a study is subsequently judged to be a "pivotal study." Some laboratories/researchers may not want to organize historical data for public release as they may see this activity as a diversion from their research priorities. There would likely also be additional costs that occur at an institutional level (i.e., Institutional Review Boards) that would be substantial. The EPA may need to find creative ways to offset the expense associated with data submission for pivotal studies.

Processing and documenting data and models developed prior to the effective date of the rule

The SAB notes that processing and documenting data and models developed prior to the effective date of the rule will pose challenges. It is likely that some flexibility is going to be required as the standards on transparency are evolving, and data collection expectations do not apply to historical studies or investigations completed 10 or 20 years ago. It is reasonable to apply modern standards of transparency and public availability to current and future studies, but it will not always be possible to apply these same standards retrospectively.

It is not clear: (1) how many of the studies EPA currently relies upon to take important regulatory actions would meet the public disclosure standards stated in the Proposed Rule, and (2) whether EPA has assessed the feasibility of making underlying information from the studies publicly available, or what the impact of precluding those studies would be on EPA's decision making and its ability to protect public health/environment. The SAB could advise EPA on how to use data from historical studies in regulatory decisions. This may require case-by-case approaches.

Prospective or retrospective application of provisions for ensuring the public availability of data and models underlying pivotal regulatory science

As previously noted, the retrospective application of modern transparency standards is a challenge. A large amount of work would be required to locate, curate and retrospectively make datasets available for public access. This requirement could adversely affect the ability to move this program forward in a meaningful capacity. EPA could decide not to apply the Proposed Rule and its specific requirements retrospectively given the potential difficulty accessing, reviewing and making data available that were not originally intended to be disseminated in such a manner

as defined in a future rule. The EPA could consider designating a "start date" and begin collecting and releasing pivotal study data at that time. When the EPA updates an existing risk assessment after the start date, the EPA could collect and release pivotal data.

Feasibility of developing criteria to specify exceptions to the requirement to make information available to the public

The Proposed Rule indicates that the EPA Administrator may grant exceptions to the requirements of the Proposed Rule on a case-by-case basis if it is determined that compliance is impracticable because: (1) it is not feasible to ensure that all pivotal regulatory science is publicly available in a manner sufficient for independent validation, consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security; or (2) It is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions. The SAB understands the need for exceptions and recommends that EPA develop specific criteria for such exceptions as part of the Final Rule. Although it may be difficult to develop criteria for exceptions, outlining such criteria would benefit EPA and help ensure that the principles of transparency outlined in the Proposed Rule are accomplished.[16]

The SAB notes that the proposal to use a case-by-case "waiver" may not be an effective mechanism for ensuring that the EPA can appropriately consider important studies, including those that rely on confidential data. Without pre-defined criteria for such waivers, a case-by-case waiver may create concerns about inappropriate exclusion of scientifically important studies. Reference to a vague "feasibility" standard suggests that such waiver decisions are to be made solely by the Administrator. In the absence of clear guidance, such waivers might appear to be inconsistent or lacking objectivity. A framework and/or guidance document could also help EPA to clarify how current scientific review procedures will be affected by this rule. It might be useful for the EPA to consider recommendations from a scientific advisory committee when making waiver decisions.

The SAB finds that exclusion of segments of the scientific literature, with the possibility of inclusion of other selected information without pre-defined criteria, could allow systematic bias to be introduced with no easy remedy. The proposed exception process applies no constraints on how this mechanism could be used or that it be restricted to the issue of confidential data. Such a proposal is inconsistent with the scientific method that requires all credible data be used to understand an issue and to allow systematic review to evaluate past research. It may be useful for the SAB to peer review documentation containing the mechanisms for exclusions based on criteria defined by EPA and provide constructive considerations.

Although it would be difficult to develop, the EPA could benefit from preparing a framework and/or guidance that outline criteria to specify exceptions. While the EPA cannot address all circumstances and scenarios that could limit data sharing, the SAB recommends that EPA explore and document some reasonably anticipated scenarios that could be described, perhaps

[16] Some members of the SAB find that conclusions from studies that cannot be independently verified and reproduced due to unavailability of data or models should not be treated as pivotal for regulatory action if the regulatory action is supposed to be based on independently verifiable and reproducible science – which might be construed as part of the definition of "sound" science.

with case studies from previous risk assessments (e.g., What information would fall in scope based on past risk assessments? What data would have to be released to support a given risk assessment? Is it feasible to release this information? Why or why not?).

3.4. Requirement to Make the Data Underlying any Rule Publicly Available

The SAB notes that there are legitimate legal, ethical, professional and financial reasons why researchers may be unable or unwilling to fully share "data" - including statutes protecting participant privacy, experimental protocols assuring confidentiality of data for human subjects, and (for past studies) issues related to degradation and custody of data. The EPA, the U.S. Office of Management and Budget, and scientific institutions have recognized these legitimate concerns, and recognized that such constraints on availability of data do not prevent studies from being verified in other ways - or preclude those studies from being considered in regulatory decisions.[17,18,19,20]

Under the Proposed Rule, EPA would require that data underlying any proposed rule be made publicly available. The SAB finds that the requirement in the Proposed Rule that "data" be made publicly available is vague and, as a result, can be interpreted in different ways. The term "publicly available" is also vague and should be better defined. If "data" includes all machine output associated with analysis it would create demands on researchers that would be very onerous and could significantly slow down science-based decision-making. Even if the "data" were accessible, making it publicly available in a useable form would be costly and could be of limited utility based on past experience of the scientific community relative to the interpretation of the derivative data. If the data required to meet the "data" requirement is no more than the current standard of most journals (and in most cases provided in supplementary information) then the implications prospectively are minimal. Either way retrospective application of the requirement would be difficult to implement, could be expensive with no clear responsibility regarding who would cover the added costs, and could arbitrarily impact the conclusions drawn.

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[17] U.S. EPA. 2016. *Plan to Increase Access to Results of EPA-Funded Scientific Research* states "some research data cannot be made fully available to the public but instead may need to be made available in more limited ways," but says the lack of full public availability "does not affect the validity of the scientific conclusions from peer-reviewed research publications." https://www.epa.gov/open/plan-increase-access-results-epa-funded-scientific-research

[18] U.S. EPA. 2002. *Information Quality Guidelines*: recognizes that sometimes "access to data and methods cannot occur due to compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections." But where that is the case "EPA should, to the extent practicable, apply especially rigorous robustness checks to analytic results and carefully document all checks that were undertaken." https://www.epa.gov/sites/production/files/2019-08/documents/epa-info-quality-guidelines_1.pdf

[19] U.S. Office of Management and Budget. 2002. *IQA Guidelines*: "[making the data and methods publicly available will assist in determining whether analytic results are reproducible...the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections... where public access to data and methods will not occur due to other compelling interests, agencies shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken."

[20] National Academy of Sciences. 2018. Letter to Acting Administrator Wheeler from Marcia McNutt, President of the National Academy of Sciences, C.D. Mote, Jr., President of the National Academy of Engineering, and Victor J. Dzau, President of the National Academy of Medicine 2 (July 16, 2018) stated that "Individual study quality should be evaluated on the basis of information that is available in standard journal articles, such as the study design elements, analytical techniques, and statistical methods. Researchers may be contacted to answer questions about the conduct of the study or be asked to provide additional data. If the study data are not available, their absence may affect how the study is rated and used in the analysis, but the study should not necessarily be eliminated from the assessment."

The Proposed Rule should be explicitly prospective and follow evolving norms developed by the scientific community as well as federal agencies (e.g., National Science Foundation, National Institutes of Health, National Oceanic and Atmospheric Administration, Department of Energy). The Proposed Rule should state and/or compare its objectives with existing and evolving federal procedures to address the underlying purpose of the Proposed Rule, which is to increase transparency of scientific studies utilized in regulatory actions. This additional explanation will enhance the characterization of the proposed regulation and will help EPA meet its objectives effectively and efficiently.

There appears to be consistency among analyses of how to address transparency that are orthogonal to the Proposed Rule. There is minimal justification provided in the Proposed Rule for why existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate, and how the Proposed Rule will improve transparency and the scientific integrity of the regulatory outcomes in an effective and efficient manner. It is plausible that in some situations, the Proposed Rule will decrease efficiency and reduce scientific integrity, determining if in fact that will be the case requires a thorough and thoughtful examination that is currently absent in the Proposed Rule. Moving forward with altered transparency requirements beyond those already in use, in the absence of such a robust analysis, risks serious and perverse outcomes.

Definition of data

The term "data" was not defined in the Proposed Rule and the nature of the data that must be made publicly available to fulfill the requirements of the Proposed Rule is not clear. It is difficult to develop a singular definition of "data" that would meet EPA's objectives in the Proposed Rule. The SAB notes that EPA has further defined "data"[21] in the supplemental proposal and, as previously discussed, the SAB finds that EPA could benefit from using the term "analysis dataset" (i.e., data that have been collected and processed for analysis) to define data. However, the definition of data would likely differ based on available datasets. For example, the original data for an in vivo study could include all the individual animal body weight or individual pathology data while a dataset for an in vitro study may include multiple samples and assays assessed, and for epidemiology data it may include individual exposure monitoring data or biological samples.

"Raw" data (also known as original or primary data) could include individual sample values collected on individual study subjects or various instruments and include each measurement on sampled endpoints (and each time it is sampled) in a given study. The original or "raw" data would not be manipulated in any fashion (e.g., removing outliers - data would appear in the raw data with a scientific rationale on why a data point was removed from subsequent analysis).

Notably, in 40 CFR part 792 -TSCA which describes Good Laboratory Practices (GLP), raw data is defined as "any laboratory worksheets, records, memoranda, notes, or exact copies thereof,

[21] Supplemental proposal definition of data: "Data means the set of recorded factual material commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as keystroke or coding errors, have been removed and that is capable of being analyzed by either the original researcher or an independent party."

that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study." All or none of this original information may or may not be needed to adequately understand the results of the study or EPA's use of the information. Thus, making all this information publicly available may be resource intensive and provide limited utility. The SAB recommends that EPA use the term "analysis dataset."

The SAB notes that the requirement to make data available for public inspection will be more easily implemented for some datasets than others (e.g., GLP studies include individual sample data as part of standard reporting). The expectation that data and methods will be available for all endpoints may be unrealistic. EPA could consider designating scores for information availability with the highest tier assigned to studies that define methods (e.g., protocol) as well as raw (individual sample level) data. Additional scores could be driven by sharing data on other related endpoints in the pivotal study to facilitate data interpretation. Scores could subsequently be used to evaluate data utility, uncertainty, etc. Ultimately, there are some datasets where CBI and/or PII data will require more onerous steps to protect data confidentiality. Based on EPA responses to SAB questions, it appears that the Agency is seeking approaches to manage these data issues.

In defining data, it might be reasonable to consider the initial compilation of data (original data) in a spreadsheet as "raw" data. While this might still require some interpretation, e.g., abbreviations used in spreadsheet column headings, and footnotes about missing data points (if they were discarded because of legitimate reasons, such as known mistakes or statistically-determined outliers), the spreadsheets are still very close to the initial raw data coming out of an instrument or written by a researcher when working with a subject in an epidemiological study.

As previously stated, it is difficult to evaluate the impacts of a definition of data a priori. There is extensive work required to understand the implications of different definitions across a diversity of fields, data types and data of different ages. Such an effort is beyond the scope of what the SAB can undertake with the resources and time available. However, the SAB finds that such an analysis is foundational to the development of any transparency rule that goes beyond well-established norms and procedures.

Another aspect to consider is the practical aspect of actually conducting a reanalysis of a major epidemiological study. Such an enterprise requires an enormous amount of work even for a well-qualified researcher. The Health Effects Institute (HEI) established a model for conducting such a reanalysis in its 2000 reanalysis of the Six Cities and American Cancer Society datasets (HEI, 2000). However, HEI has not repeated this kind of exercise. EPA could consider using the HEI model for funding its own reanalysis for datasets that are deemed critically important for regulation.

3.5. Requirement to Describe and Document any Assumptions and Methods Pertaining to the use of Data and Models Underlying Pivotal Regulatory Science

The Proposed Rule requires the EPA to describe and document any assumptions and methods that pertain to the use of data and models underlying pivotal regulatory science and to describe variability and uncertainty. The SAB notes that high quality scientific studies identify the assumptions used in models and methods, the variability of the replications, and any other confounders that add to the uncertainty of the final dataset, so these are not unusual or inappropriate factors to be addressed. Specifically, it is good practice to identify: (1) testable

assumptions (e.g., that residuals in a regression model are normally distributed with constant variance); (2) results of tests of assumptions; and (3) any untested assumptions made in deriving conclusions from data (e.g., that there are no unmeasured confounders, or that dose-response functions are linear below the lowest dose for which data are available). Results of tests should be presented where they are available, and assumptions that have not been tested, or that have been tested but not supported, should be identified. Assumptions are often made about (a) error distributions for exposure estimates (most commonly, that they can be ignored); (b) model specification errors and uncertainties; and (c) causal interpretations of modeling results. These assumptions should be explicitly stated, and results of tests presented. Epidemiologists (e.g., Sander Greenland), statisticians, and risk analysts have written at length over several decades about how to test, validate, and document assumptions and methods for dose-response modeling and uncertainty and variability characterization, and these modern methods should be applied to make the factual and assumption-based foundations of pivotal studies as clear as possible. However, the SAB finds that there are scientific and technical challenges to be overcome and provides suggestions to implement this requirement.

Currently, in various chemical assessment processes, EPA program offices attempt to document the methods, assumptions, variability and uncertainty associated with the use of various dose-response models and data inputs utilized. EPA has generally done this in a qualitative format and should continue to refine and document this information. One would anticipate variability in the reporting of assumptions, methods, variability, and uncertainty across laboratories. Therefore, EPA could offer guidance on how to report these parameters. When this information is received from submitting laboratories, EPA could review the information to determine if methods, uncertainty, etc. are adequately addressed, and the Agency could follow up as needed. There are numerous resources available from which the EPA could develop guidance, including some defined by the EPA (Maurissen, 2010; U.S. EPA, 2012; U.S. EPA, 2019). The SAB notes that it may be difficult to make detailed information available to the public for some parameters like methods. This will vary depending on factors such as how new/novel the method is, how many variables impact outcome, etc. Many laboratories may not want to share standard operating procedures for public release by the EPA.

Dose response models

The following language in the preamble of the Proposed Rule has been interpreted differently by some members of the SAB:

> "…there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects. The use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions. To be even more transparent about these complex relationships, EPA should give appropriate consideration to high quality studies that explore: A broad class of parametric concentration-response models with a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the exposure range; and spatial heterogeneity. EPA should also incorporate the concept of model uncertainty when needed as a default to optimize low dose risk estimation based on major competing models, including linear, threshold, and U-shaped, J-shaped, and bell-shaped models."

Some SAB members view this as a policy change indicating that evidence of nonlinearity should not be ignored when there is scientific evidence to support it. They note that EPA has explicitly identified low-dose linear models, along with others, in the list of models to be considered, and that support for alternative models is indicated in the EPA's 2005 Cancer Guidelines (U.S. EPA, 2005). On page 1-8 the EPA Cancer Guidelines state:

> "When there are alternative procedures having significant biological support, the Agency encourages assessments to be performed using these alternative procedures, if feasible, in order to shed light on the uncertainties in the assessment, recognizing that the Agency may decide to give greater weight to one set of procedures than another in a specific assessment or management decision. Encouraging risk assessors to be receptive to new scientific information, NRC discussed the need for departures from default options when a sufficient showing is made."

Additionally, in the National Academies 2009 Report *Science and Decisions* (page 207) (NRC, 2009) the Committee recommended that "EPA should continue and expand use of the best, most current science to support or revise its default assumptions." The Committee also identified several factors that EPA should take into consideration, including: "(1) the extent to which the current default is inconsistent with available science; (2) the extent to which a revised default would alter risk estimates; and (3) the public health (or ecologic) importance of risk estimates that would be influenced by a revision to the default."

Conversely, other members of the SAB view the language in the preamble of the Proposed Rule cited above as inappropriately codifying certain required scientific approaches into regulation. In support of this view, some members note that: (1) the preamble of the Proposed Rule asserts without providing any evidence that "there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects," and (2) the preamble does not acknowledge the value of default models (in this regard, these members also note that the National Academies' 2009 Report *Science and Decisions* (NRC, 2009) specifically recommended the use of non-threshold and linear models as a default for both cancer and non-cancer dose-response analysis). It is critical that the justification for alternative approaches is well documented and transparent, and some members of the SAB find that is not currently the case.

It is important that the EPA provide clarity as to the Agency's intent. Therefore, the SAB recommends that the preamble of the Proposed Rule include some specific examples or case studies where there is evidence in the published literature demonstrating threshold or other low-dose nonlinear responses which provide support for the preamble statements (e.g., Sweeney et al., 2009; Johnson et al., 2014; Cohen et al., 2016). The SAB notes that the EPA's 2005 Guidelines for Carcinogen Risk Assessment allow the Agency to consider nonlinear approaches after an analysis of available data under the guidance provided in the framework for mode of action analysis. Notably, where alternative approaches have significant biological support, and no scientific consensus favors a single approach, an assessment may present results using alternative approaches (i.e., a nonlinear approach). It may be useful for the Agency to consider

developing guidance or criteria delineating when data may be sufficient to apply alternative approaches. [22]

In general, it is difficult to define universal "rules of good behavior" for a many-faceted question such as choosing the right dose-response model. In some situations, direct biological arguments may support a particular model such as a linear or log-linear dose-response model. Where information on kinetics (e.g., saturable metabolism) as it relates to the dose-response is available, this might help guide selection of the most appropriate model. In other cases, the use of any model as a default choice may be inappropriate. The biostatistics literature includes many procedures for identifying and validating appropriate models, including techniques such as Bayesian Model Averaging which avoid the specification of a single model. There is no "one size fits all" approach that could be applied to all problems of this nature.

3.6. Protecting Sensitive Data and Copyrighted or Confidential Business Information

The Proposed Rule preamble states that nothing in the Proposed Rule compels the disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections**.** The SAB provides suggestions and recommendations to protect sensitive data and copyrighted or confidential business information.

It seems reasonable that the standards applied by the EPA should be the same as the standards applied by editors of reputable scientific journals. A report of the National Research Council (NRC, 2003) discusses responsibilities of authors to share data, software, and materials related to their publications. Techniques and practices to protect sensitive data have been developed by researchers involved in studies with human subjects. Other federal agencies have utilized specific and explicit data transfer agreements with entities that sought access to protected information for the purposes of reviewing and running analysis on the dataset. The EPA could employ similar approaches. Any new rule needs to build on those efforts. Coding data to protect any personal identifiers is routinely done and may have already been done with the datasets under consideration. If aggregation of some of the data (e.g., by age bands) does not compromise the ability of the calculations to be done, then this would protect personal information. Existing methodologies and technologies already in widespread use such as those used in NHANES III (National Center for Health Data Statistics, 2019), including multiple imputation, can be used to provide protected access to data. Additional technologies worth considering include differential privacy techniques (Dankar and El Emam, 2012) and perhaps Bayesian deep learning and other approaches that model joint distributions for variables in a dataset and that can use them to generate anonymous data exchangeable with the original data.

As previously mentioned, the Agency could develop tiers of public access that may include a base level of information (e.g., a robust summary or final study report which is devoid of

[22] One SAB member notes that the Proposed Rule emphasis on consideration of studies that use a diversity of models is arbitrary. The member points out that there is no scientific basis provided in the Proposed Rule for giving greater weight to studies that use a wider variety of models without regard for goodness-of-fit, confidence bounds, biological plausibility, attention to untested assumptions. The member notes that the lack of a scientific basis for this approach and the lack of transparency with respect to the logic underlying the proposed approach undercuts confidence that goals of the proposal can be accomplished without perverse effects. The member also notes that this indicates the need for a peer-reviewed transparent analysis in which all assumptions, data and conclusions are made available to the public before the Proposed Rule is enacted.

confidential protected information) for the general user or member of the public and then require additional information or when access to confidential or copyrighted information is warranted. Copyright would protect the particular program or model from being used by others without permission. Signing a non-disclosure agreement would protect other CBI information. A model for accessing personal information contained in federal datasets already exists in the Federal Statistical Research Data Centers (FSRDCs), where individual researchers can access individual-level data under conditions that guarantee the confidentiality of personal information. EPA could consider collaborating with other federal agencies to provide access through the FSRDCs for federal data that are used in epidemiological research (e.g., Medicare data).

The SAB notes that many publications supported by federal grants are freely available in the public literature and this may reduce the concern about publication of these data. For data that are published, but not freely available, the Agency could consider paying a fee to make these data publicly available (e.g., an open access fee). This might protect the rights of journals to copyrighted material.

For CBI and PII, it is possible that access may be possible, but limited in some cases. For example, members of the public could petition the EPA for access to some sensitive data and the Agency could take countermeasures to provide only the information permissible and control the settings around which these data are made available (e.g., onsite access only). This option would likely require the EPA to maintain a “data office” which would require substantial resources to establish and support.

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APPENDIX A: DISSENTING OPINIONS

1. Dissenting Opinion from Dr. John Graham

Dr. Graham's individual comments on EPA's proposed rule, Strengthening Transparency in Regulatory Science are provided in:

U.S. EPA Science Advisory Board. 2019. *Consultation on Mechanisms for Secure Access to Personally Identifying Information (PII) and Confidential Business Information (CBI) Under the Proposed Rule, Strengthening Transparency in Regulatory Science.* EPA-SAB-19-005. pages B-16 to B-20. [Available at: https://yosemite.epa.gov/sab/sabproduct.nsf/41042C652229CA398525848500595458/$File/EPA-SAB-19-005.pdf]

2. Dissenting Opinion from Dr. Donald van der Vaart

Addendum to the SAB's consideration of EPA's proposed rule titled *Strengthening Transparency in Regulatory Science*

By Donald R. van der Vaart

While the points raised by the SAB are valuable, the criticism of the transparency rule is overly one-sided. What must be weighed against the inherent challenges for such a rule is the serious problem that currently exists with EPA science and that has eluded the Data Quality Act. Instances of fraudulent science in academic institutions are a reality. As a relatively small illustration, Duke University Medical Center recently settled a whistle-blower suit for more than $100 million for allegations research was fabricated, some of which was done for EPA standard setting. Speaking to the press the whistleblower's lawyer noted that his client's suit was motivated, in part, by,

"…his concerns that the university wasn't being transparent enough, after "Duke's administration and researchers faced the reality that seven years of data were false or unreliable." https://www.npr.org/2019/03/25/706604033/duke-whistleblower-gets-more-than-33-million-in-research-fraud-settlement

Transparency is not something academic institutions crave, but when they accept hundreds of millions of taxpayer dollars those taxpayers deserve some level of meaningful transparency. EPA's proposed rule seeks to do that. Studies undertaken to protect the health and welfare of Americans are crucially important. While conventional wisdom appears to assume added scrutiny would necessarily weaken a standard, I am equally concerned standards might not be protective enough as a result of spurious or fraudulent science.

The proposal should be applauded in its efficiency. When an agency such as EPA relies more on some studies than others, it is natural to seek added scrutiny to those "pivotal" studies. As an example, when only a few studies formed the basis of costly standards for PM 2.5, such as the Harvard Six-City and CPS-II studies, the importance of allowing peer scientific groups to review

and potentially replicate the results is greater, and every effort should be made to provide for such review.

While the SAB's comments should be considered and answered in either the final rule or in subsequent guidance, the importance of the rule should not be lost. The EPA proposal is a thoughtful approach to the admittedly difficult challenge.

Exhibit C

The Final Strengthening Transparency in Regulatory Science (STRS) Rule
Differing Scientific Opinion
Thomas Sinks, Ph.D
Humans Subjects Research Review Official

Summary:

1. The STRS must align with EPA's Scientific Integrity Policy (SIP) because the rule instructs scientists how to select, analyze, and interpret the science underlying rulemaking.
2. The SIP supports EPA scientists providing their differing scientific opinions.
3. The [draft] final rule includes fatal flaws that will prevent the Agency from achieving its mission:
    a. The final STRS reliance on a tiered system (Secure Data Enclave) is infeasible and there is no evidence that, if established, an SDE could achieve the goal of the STRS.
    b. As a result, the weighting scheme will force EPA scientists to discount or ignore human subjects research results that include the best available science in health-based rule making.
4. EPA scientists will be unable to practice scientific integrity, our agency will develop poor health-based rules, and the public may not be protected from environmental exposures.

Findings:

Why is the STRS subject to EPA's Scientific Integrity Policy?

The EPA Scientific Integrity Policy states …EPA's policymakers involve science experts on scientific issues and that the scientific information and processes relied upon in policymaking manifest scientific integrity, quality, rigor, and objectivity.[1] EPA's Scientific Integrity Policy applies directly to the STRS because it defines how agency scientists *review data, models, and studies at the time a rule is developed or influential science is finalized.*[2]

What qualifies me to provide a differing scientific opinion?

The EPA Scientific Integrity Policy states …*When an Agency employee substantively engaged in the science informing an Agency policy decision disagrees with the scientific data, scientific interpretations, or scientific conclusions that will be relied upon for said Agency decision, the employee is encouraged to express that opinion, complete with rationale, preferably in writing*.

1) I have been an EPA employee since September 6, 2015 when I was hired as the Director, Office of the [EPA] Science Advisor.

2) I am the principal author of EPA's *Plan to Increase Access to Scientific Results of EPA-funded Research*.[3] In addition, I have represented EPA on the National Science and Technology Council's Open Science Workgroup and Subcommittee since 2016.

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[1] EPA Scientific Integrity Policy … https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf
[2] https://www.federalregister.gov/documents/2020/03/18/2020-05012/strengthening-transparency-in-regulatory-science
[3] https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

3) I was named by the Office of the Administrator (OA) as the Agency point-of-contact in the Notice of Proposed Rulemaking for Strengthening Transparency in Regulatory Science in the spring of 2018.

4) I participated as a member of the ORD team addressing the science issues raised in comments on the proposed rule - Strengthening Transparency in Regulatory Science.

5) In have 35 years of experience as a Federal government epidemiologist. I have conducted, analyzed, reviewed, and published human subjects research including cohort, case-control, cross-sectional, and community intervention trials. From 2005 to 2015, I was the Acting Director and the Deputy Director of both the National Center for Environmental Health at the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

6) I have served as EPA's Humans Subject Research Review Official since August 2016. I was the principal official updating EPA's revision to the Common Rule. I am the only EPA scientist that has worked to establish a tiered approach to access Confidential But Unclassified Information (CUI) using a Secure Data Enclave.

Why is a Secure Data Enclave not a feasible mechanism for supporting the STRS?

EPA's *Plan to Increase Access to Scientific Results of EPA-funded Research* (Plan) requires that the data underlying EPA intramural and extramural published science be made available through designated data repositories. The purpose underling the Plan is to provide researchers the opportunity to extend Federal investments in research by further analyses of the data or combining the data sets with additional data. In contrast to the STRS, the Plan is not intended to make underlying data available to external scientists to evaluate falsification or fabrication (scientific misconduct) or alternative statistical approaches to analyses.

The EPA Plan has been implemented in three phases and covers the underlying datasets of studies published after implementation. Data underling ORD intramural publications have been made available since October 2015. Data underling other intramural datasets have been made available as of October 2018. The EPA Plan does not cover datasets underlying EPA-funded publications prior to the implementation dates nor studies reviewed by EPA that were not funded by EPA (3rd party research). While every Federal Agency having a research portfolio of $100 million has published a similar plan, EPA has no agreements in place with any Federal, state, or local agency, academic institution, trade association, industry, or contract research company to host their data on EPA's data repository (Science Hub). No EPA policy order, guidelines, or regulations exist that encourage or enable EPA to collect 3rd party research data and host it in our data repository.

The EPA plan recognizes the need to promote public access while protecting CUI data. However, the plan does not establish a mechanism to promote the availability of personal identifying/health information (PII/PHI) or confidential business information (CBI). One mechanism for promoting access to CUI data is a tiered access system within a Secure Data Enclave (SDE). However, EPA has not established an SDE and lacks trained staff or funding to manage an SDE. Recognizing that the Plan implies a need to make EPA-funded CUI data available for analysis and recognizing that EPA had neither the staff expertise nor funding to create one, Greg Susanke and I established an interagency agreement

(IA) with the Data Research Center (RDC) of National Center for Health Statistics, Centers for Disease Control and Prevention. We created a pilot study using the RDC to host no more than 5 EPA intramural datasets. It took 18 months to establish the interagency agreement. At this time, one dataset underlying EPA research has been posted. We have confirmed that EPA lacks the technical expertise or training to create our own SDE. We confirmed that rigorous data management plans and data security are required. We believe the cost to use the NCHS RDC ($250K to post up to 5 sets of data for 3 years) would be prohibitive for a larger effort.

We note that our pilot was established to support the EPA Plan, not the proposed STRS rule. It seems unlikely that EPA could establish our own SDE in less than two years and without a sizable financial investment. In addition, it does not appear feasible that an EPA SDE could host datasets of 3rd party research, research published prior to 2015, or research covered by a Certificate of Confidentiality (CoC)[4]. EPA cannot mandate 3rd party research being posted on an EPA owned or shared SDE. Approval to post historic datasets must be reviewed by the original IRB which may or may not agree. In some cases, reconsent of human subjects may be required which would prevent any effort to reanalyze the published dataset. The impact of the 21st Century Cures Act may also limit the use of an SDE. Under a CoC, data sharing of PII/PHI is limited between the investigators. All NIH and CDC human subjects research conducted since the fall of 2016 when the 21st Century Cures Act was finalized is covered by a Certificate of Confidentiality. The vast majority of environmental human subjects research is conducted by agencies other than EPA.

Finally, restricting access through an SDE may fail to meet EPA's definition used in the STRS supplemental rule of public availability … *available in a manner sufficient for independent validation*. The SDE will enable data analysis of restricted data but not access to the data. The SDE prevents disclosure of direct or indirect identifiers which an analyst may require to establish independent validation.

Why would a weighting scheme based on underlying data unavailability result in inferior health-based rulemaking?

Any rule or guidance that diminishes or removes high quality research from consideration in rule making results in poorly developed rules. Factors used to define high quality research are study type, design, quality control measures and how the findings fit into a weight-of-evidence supporting or refuting causation[5]. The availability of underlying data provides a platform for new research and may allow the public to verify analyses or demonstrate errors, falsification, or fabrication of the findings.
But data availability is not a measure of study quality nor is it a determinant of causation.

Human subjects research is the most predictive data for establishing the human health impact from environmental exposures. The double-blind placebo trial is considered the gold standard. Community trials also provide high quality information. Observational studies are also informative, particularly occupational cohort studies. Case-control and cross-sectional research is less informative and significant

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[4] Wolf LE, Beskow LM. New and Improved? 21st Century Cures Act Revisions to Certificates of Confidentiality. American Journal of Law and Medicine. 44(2018): 343-358

[5] Weed DL, Gorelic LS; The Practice of Causal Inference in Cancer Epidemiology. Cancer Epidemiol Biomarkers Prev 1996 Apr;5(4);303-311.

control for confounders is required. Known human carcinogens receive that classification only if high quality human health studies document an increased cancer risk.

Conclusion:

Human subjects research data are protected from unrestricted public access. The Privacy Act, Common Rule, HIPPA, and the 21st Century Cures Act all contribute to these protections. As described above, restricted access using a SDE is not a solution. A final STRS rule that diminishes or disregards highly relevant human subjects research from consideration because of underlying data availability and relies too heavily on a nonexistent SDE will result in setting aside relevant science in developmental phases of rulemaking. This will compromise the scientific integrity of our scientists, the validity of our rulemaking, and possibly the health of the American People.

Exhibit D

EDF
ENVIRONMENTAL
DEFENSE FUND
Finding the ways that work

May 18, 2020

SUBMITTED VIA REGULATIONS.GOV

Administrator Andrew R. Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

ATTN: DOCKET NO. EPA-HQ-OA-2018-0259

RE: COMMENTS OF ENVIRONMENTAL DEFENSE FUND ON EPA'S SUPPLEMENTAL NOTICE OF PROPOSED RULEMAKING: "STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE," 85 FED. REG. 15,396 (MAR. 18, 2020) ("SUPPLEMENTAL NOTICE")

Administrator Wheeler:

On behalf of our over 2.5 million members and supporters, Environmental Defense Fund (EDF) strongly opposes the Environmental Protection Agency's (EPA) March 18, 2020, Supplemental Notice to sharply curtail the agency's ability to use the best available science in making decisions about vital public health and environmental protections.[1] Cynically presented under the guise of promoting "transparency" in EPA's use of science, the Supplemental Notice would in fact *censor* science at EPA by radically expanding upon an April 2018 proposal to bar the agency from using rigorous, peer-reviewed health studies that rely on confidential data. Like its predecessor proposal, the Supplemental Notice lacks any legal or factual basis; would undermine the scientific integrity of the agency's decisions; and would do deep damage to public health by blinding the agency to life-saving research and hobbling the agency's ability to carry out our nation's bedrock health and environmental laws. EPA must immediately withdraw this harmful, misguided, and fatally deficient proposal.

[1] Strengthening Transparency in Regulatory Science, 85 Fed. Reg. 15,396 (Mar. 18, 2020).

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As we explain in these comments, the Supplemental Notice fails to rectify any of the fundamental flaws in the original proposal. Rather, it exacerbates them by expanding the scope of that flawed proposal to *all* data and models used by the agency, and to a vast universe of influential scientific information produced by EPA. Ignoring concerns that the original proposal would either require researchers to disclose confidential personal and medical information or restrict EPA from using those studies, the Supplemental Notice alters the definitions in the original proposal to make explicit that "[p]ersonnel and medical information . . . the disclosure of which would constitute a clearly unwarranted invasion of personal privacy . . . are intended to be subject to this rulemaking."[2]

Other changes to the original proposal that are reflected in the Supplemental Notice likewise do nothing to mitigate the concerns that numerous commenters, including EDF, pointed out in prior comments. For example, the Supplemental Notice's suggested new approaches for implementing restrictions on the agency's use of science amount to a disingenuous attempt to arrive at the same unlawful and arbitrary result as the original proposal, through only superficially different means, and lack either the reasoned justification or level of detail needed to allow for meaningful comment.

Our comments, among other things, point to these central defects in the Supplemental Notice:

- Like the original proposal, the Supplemental Notice fails to identify a problem that it is needed to address, and rests on the false premise that studies that draw on confidential data are not sufficiently reliable to inform agency decisions. Nowhere does the Supplemental Notice acknowledge or respond to the voluminous evidence in the record—including statements by leading scientific institutions and scientific publications—reaffirming that the availability of underlying data is neither necessary nor sufficient to assure the reliability of a study.

- EPA's novel claim that the federal "housekeeping" statute authorizes the agency to issue a substantive rule permitting it to ignore the best available science is preposterous—contradicting both the plain language of the statute and case law indicating that a sweeping, binding rule of this kind is not a "housekeeping" rule within the scope of the statute. The Supplemental Notice, like the original proposal, would also violate numerous statutes that require EPA to either use "best available science" or to otherwise examine all available data when issuing health or environmental protections. The housekeeping statute provides no authority for EPA to violate those statutes.

[2] *Id.* at 15,401 (alteration in original).

- EPA's new proposals to permit consideration of studies only where the underlying data has either been publicly disclosed or shared through "tiered access" arrangements, or to give less weight to studies where the underlying data has not been disclosed, would result in arbitrary and unjustified exclusion of studies based solely on the availability of data—including in situations where those studies have been validated by other means, and where there are legitimate legal, ethical or practical constraints that prevent disclosure of the underlying data. EPA has also failed to acknowledge or consider important and relevant factors such as the cost of implementation and the impacts of these options on the studies it may consider.

- The Supplemental Notice, like the original proposal, has "entirely failed to consider" virtually every "important aspect of the problem" it purports to address,[3] including the costs of the proposal for researchers, EPA, and the public; the numerous practical, legal, and ethical constraints that make it difficult or impossible for researchers to disclose data and models in many cases; and the effectiveness of reasonable alternatives to EPA's draconian proposal, including traditional methods of peer review and consultation with expert advisory boards. Despite having worked on this proposal for two years, EPA has *still* failed to assess the number and type of studies the agency would no longer be able to consider under this rule—even though the Congressional Budget Office has previously found that similar legislative proposals could sharply curtail the agency's ability to use thousands of scientific studies and cost the agency hundreds of millions of dollars per year.[4] That the Supplemental Notice vastly extends the scope of the original proposal, to cover a far larger range of data and models and a much broader universe of EPA actions and work products,[5] only exacerbates EPA's continued failure to evaluate the costs and impacts of this proposal.

[3] *Motor Vehicle Mfrs. Ass'n v. State Farm Ins*., 463 U.S. 29, 43 (1983).

[4] *See* Susanne S. Mehlman, Jon Sperl & Amy Petz, Cong. Budget Office, Cost Estimate for H.R. 1030: Secret Science Reform Act of 2015 at 2-3 (Mar. 11, 2015) ("CBO expects that EPA . . . would base its future work on fewer scientific studies . . . . CBO expects that the agency would probably cut the number of studies it relies on by about one-half . . . ."); Susanne S. Mehlman, Jon Sperl & Amy Petz, Cong. Budget Office, Cost Estimate for S. 544, Secret Science Reform Act of 2015 (June 5, 2015) ("CBO Estimate for S. 544") (estimating that another similar congressional proposal would cost up to $250 million per year).

[5] The original proposal only covered studies and dose-response data and models used to support "significant regulatory actions." 83 Fed. Reg. 18,768, 18,771 (Apr. 30, 2018). As noted above, the Supplemental Notice would expand that coverage by (a) applying to all data and models, not just those in dose-response studies, and defining "model" about as broadly as is conceptually possible, as "a simplification of reality that is constructed to gain insights into select attributes of a physical, biological, economic, or social system," 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2); and (b) applying the proposed requirements not just to data and models supporting significant regulatory actions, but to data and models supporting "influential scientific information" as well, *id.*, a broadly defined category of EPA products that includes numerous documents that are vital to EPA regulations and policies.

- The Supplemental Notice's revised provisions allowing the Administrator to waive the requirements of the proposal on a case-by-case basis continue to leave the door open to selective and biased application of its requirements—allowing the Administrator to arbitrarily consider only those studies that support a desired conclusion.

- The Supplemental Notice, like the original proposal, suffers from numerous procedural deficiencies—including EPA's failure to undertake required consultations with other federal agencies and with EPA advisory boards.

Finally, we reiterate that EPA's decision to issue this attack on public health in the midst of a global pandemic and economic crisis—with *no* opportunity for public hearing and an unreasonably short 61-day window for public comment—fails to satisfy its obligation to provide a meaningful opportunity for public input. As we explained in our March 18, 2020, request for suspension of the comment period,[6] the Supplemental Notice radically alters the scope of the April 2018 proposal and dramatically expands its practical implications; introduces an entirely new legal theory in support of EPA's effort to censor science; presents two new implementation alternatives; and makes other significant amendments to the proposal, including a slew of new regulatory definitions. Under ordinary circumstances, changes this sweeping to a proposal this consequential would require a comment period *at least* as long as the 108 days provided on the April 2018 proposal. And as EPA is aware, these are no ordinary circumstances: the same public health experts and scientists whose input is essential to this Supplemental Notice are occupied in fighting a global pandemic. Moreover, EPA has pointed to no health or environmental benefit that would justify moving forward with this rulemaking: to the contrary, this proposal would harm the public by undermining vital health and environmental protections. For these reasons, EPA's rushed comment process—and its rejection of a legally-required opportunity for hearing—violates the agency's statutory duty to provide the public with a meaningful opportunity to weigh in.

EPA must abandon this irretrievably unlawful and misguided attack on public health.

Respectfully submitted,

Dena Adler
Lance Bowman
Tomás Carbonell
Ben Levitan
Jennifer McPartland

[6] EDF, Request to Immediately Halt and Withdraw EPA's Censored Science Rulemaking Action, and Suspend Deadline for Public Comments on EPA's Supplemental Notice of Proposed Rulemaking, Docket ID No. EPA-HQ-OA-2018-0259-9336 (Mar. 18, 2020).

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I. EPA'S SUPPLEMENTAL NOTICE FAILS TO REMEDY FUNDAMENTAL DEFECTS IN THE ORIGINAL PROPOSAL

EDF's 2018 comments on the original proposal documented numerous deficiencies in the agency's reasoning and a near-total lack of factual support for the proposition that EPA should be barred from considering studies where the underlying data or models cannot be publicly disclosed. Among other things, our comments noted that the proposal failed to identify an actual problem that needed to be addressed, or to point to even a single example of an EPA action or rulemaking that was later found to be defective because it rested on a study for which data was not publicly available.[7] We pointed to statements by leading scientists and scientific institutions indicating that the central premise of the proposal—that studies resting on confidential data or models are somehow not reliable enough to inform agency decision-making—is false, and ignores the many other methods and safeguards that agencies and the scientific community routinely use to validate scientific studies.[8] And we demonstrated that almost all of the documents EPA cited in support of the proposal—including EPA policies, Office of Management and Budget (OMB) guidance, and policies adopted by scientific journals and institutions—either failed to support the proposal or flatly contradicted it.[9]

These errors amount to a clear violation of EPA's obligation to ground its decisions in reasoned decision-making, and constitute fatal legal deficiencies.[10] Despite the nearly two years that elapsed since EPA issued the original proposal, however, the Supplemental Notice fails to acknowledge—much less rectify—any of the gaping holes in logic and evidence that we identified in our comments. Compounding these deficiencies, the Supplemental Notice drastically expands the scope of the original proposal to all data and models used by the agency (not just dose-response data and models), and to data and models supporting "influential scientific information" as well as the regulatory actions that were the focus of the original proposal. For these reasons, all of the deficiencies we documented in the original proposal are even more fatal to the Supplemental Notice—and would render any final rule issued on this record unlawful, arbitrary, and capricious.

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[7] EDF, Comments on the Environmental Protection Agency's *Proposed Rule: Strengthening Transparency in Regulatory Science*, Docket ID No. EPA-HQ-OA-2018-0259-9227, at 64 (Aug. 16, 2018) ("EDF 2018 Comments").

[8] *Id.* at 17-18.

[9] *Id.* at 86-91, App. A.

[10] *State Farm*, 463 U.S. at 43 ("[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.") (citations and quotation marks omitted).

A. THE SUPPLEMENTAL NOTICE REMAINS A "SOLUTION IN SEARCH OF A PROBLEM."

An agency action is arbitrary and capricious where it fails to identify a problem that it is needed to address.[11] The Supplemental Notice, like the original proposal, runs afoul of this basic principle of administrative law.

As EDF explained in its initial comments, EPA has developed a well-earned reputation for grounding its decisions in rigorous science over approximately five decades of operation spanning administrations of both parties.[12] This reputation has not come by accident—rather, it has resulted from deliberate efforts by EPA to utilize time-tested tools including formal peer review; close scrutiny of agency policies, decisions, and studies by the agency's advisory committees and external bodies such as the National Academies; and systematic frameworks that govern the agency's review and evaluation of the scientific studies that inform its work (such as the Preamble to the Integrated Science Assessment and systematic review protocols accompanying Integrated Risk Information System (IRIS) toxicological reviews). On top of these well-established mechanisms, the ability of the public to comment on the agency's use of science—and seek judicial review of arbitrary actions—constitutes a further safeguard to ensure the agency acts on the basis of the best available science.[13]

Like the original proposal, the Supplemental Notice fails to explain why these mechanisms are insufficient—or to address other information that has emerged since the publication of the original proposal that underscores this basic flaw in the rule. EPA's own Science Advisory Board (SAB) issued a final report on this proposal in April 2020 that sharply criticized EPA's failure to consider the effectiveness of existing transparency mechanisms—and warned that the proposal could "reduce scientific integrity" and "decrease efficiency":

> There appears to be consistency among analyses of how to address transparency that are orthogonal to the Proposed Rule. There is minimal justification provided in the Proposed Rule for why EPA finds that existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate, and how the Proposed Rule will improve transparency and the scientific integrity of the regulatory outcomes in an effective and efficient manner. It is plausible that in some situations, the Proposed Rule will decrease efficiency and

[11] *See, e.g.*, *Nat'l Ass'n of Fed. Employees v. Vilsac*k, 681 F. 3d 483, 485-86 (D.C. Cir. 2012) (concluding that identifying a legitimate governmental interest without foundation that the problem exists is "a solution in search of a problem" and arbitrary).

[12] EDF 2018 Comments at 64.

[13] *Id.* at 65.

> reduce scientific integrity, determining if in fact that will be the case requires a thorough and thoughtful examination that is currently absent in the Proposed Rule. Moving forward with altered transparency requirements beyond those already in use, in the absence of such a robust analysis, risks serious and perverse outcomes.[14]

Nor does the Supplemental Notice explain what problem would be solved by barring the agency from using studies where the underlying data is not available for reanalysis—no matter what ethical, legal, or practical barriers to disclosure might exist or what other methods have been used to validate the study. EPA has still failed to cite a single example, in either the Supplemental Notice or original proposal, where an EPA action, model, or other data underlying a regulatory action has proved deficient due to lack of public access to all underlying data.[15] The Supplemental Notice likewise fails to point to a single example where influential scientific information has proven to be faulty because it was based on data that was not made available for reanalysis—even as it proposes for the first time to bar consideration of data and models in the large volume of influential scientific information that EPA produces. The Supplemental Notice, like the original proposal, is therefore a classic instance of an arbitrary "solution in search of a problem."[16]

B. The Supplemental Notice Continues to Rest on the Arbitrary Premise that a Study Is Unreliable if It Relies on Data or Models that Cannot Be Disclosed.

EDF also pointed out in its comments that the central premise of the proposal—that a study is somehow inherently unreliable if the underlying data or models have not been disclosed—is false. As leading scientists and scientific institutions have concluded, the ability to reanalyze the

[14] Science Advisory Board, EPA-SAB-20-005, Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled *Strengthening Transparency in Regulatory Science*, at 18 (Apr. 14, 2020) ("Final SAB Report").

[15] A dissenting opinion in the SAB's final report in this proposal points to a recently-settled claim of data fraud associated with EPA-funded research conducted at Duke University. Final SAB Report, at A-1. However, the dissent fails to provide any evidence that the fraudulent data materially affected any EPA regulatory action or influential scientific information. Nor does the dissent provide any evidence that the requirements in this proposal—which merely restrict EPA from using certain studies and do nothing to assure that any data disclosed by researchers is authentic—would have assisted in identifying or preventing the incident. To the contrary, the incident demonstrates that current safeguards are effective in assuring scientific integrity and provide strong incentives against fraud: the fraudulent data was discovered and reported by a fellow researcher at Duke, who ultimately received a substantial reward as part of a $112.5 million settlement with the Department of Justice. *See* Sheila Kaplan, *Duke University to Pay $112.5 million to Settle Claims of Research Misconduct*, N.Y. TIMES (Mar. 25, 2019), https://www.nytimes.com/2019/03/25/science/duke-settlement-research.html.

[16] *Nat'l Ass'n of Fed. Employees*, 681 F. 3d at 485-86; *Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F. 3d 831, 840-41 (D.C. Cir. 2006) ("Professing that an order ameliorates a real industry problem but then citing no evidence demonstrating that there is in fact an industry problem is not reasoned decisionmaking."); *Sorenson Commc'ns v. FCC*, 755 F.3d 702, 709-10 (D.C. Cir. 2011) (similar).

data underlying a study is neither necessary nor sufficient to assure the validity of the study.[17] Reanalysis addresses only one aspect of a study's reliability—the possibility of certain types of errors or misrepresentations in the study's results—and is neither the only way to validate a study nor is it even close to being the most relevant or compelling factor in gauging a study's reliability.[18] Key aspects of reasoned decision making are the requirements that an agency explain reasonably why it is exercising its discretion in a given manner, and the concomitant responsibility to consider alternatives which may be more congruent with an agency's core responsibilities.[19] A rulemaking is irredeemably arbitrary where, as here, it proceeds from an incorrect premise.[20] Likewise, rules lacking in factual support are impermissibly arbitrary.[21]

The Supplemental Notice does not in any way address this fundamental defect in the proposal. Meanwhile, information that has become available since the 2018 proposal's publication only underscores that it proceeds from a false premise. In November 2019, the editors of the nation's leading science journals issued a statement underscoring that the notion of discounting studies based on the availability of underlying data is contrary to good scientific practice and would be a "catastrophe" for public health:

> As leaders of peer-reviewed journals, we support open sharing of research data, but we also recognize the validity of scientific studies that, for confidentiality reasons, cannot indiscriminately share absolutely all data. . . . *Discounting evidence from the decision-making process on the basis that some data are confidential runs counter to the EPA stated mission "to reduce environmental risks . . . based on the best available scientific information."* . . . We urge the EPA to continue to adopt an approach that ensures the data used in decision-making are the best available, which will at times require consideration of peer-reviewed scientific data, not all of which may be open to all members of the public. The most relevant science, vetted through

[17] EDF 2018 Comments at 17-21.

[18] *Id.* at 17 & n.47.

[19] *State Farm*, 463 U.S. at 48-49 (reasoned explanation requirement), 43 (failure to consider other alternative safety measures after rejecting passive restraints was arbitrary); *see also U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 571 (D.C. Cir. 2004) (agency action overturned where agency failed to explore reasonable alternatives, including tailored alternatives to nationwide rule).

[20] *See Clean Air Council v. Pruitt*, 862 F.3d 1, 10 (D.C. Cir. 2017) (summarily vacating EPA action as arbitrary and capricious where it was based on determinations that were plainly "inaccurate and thus unreasonable").

[21] *See, e.g., Util. Solid Waste Activities Grp. v. EPA*, 901 F. 3d 414, 431, 432 (D.C. Cir. 2018) (concluding rule resting on "unsupported suppositions" where there was "no evidence in the record supporting the EPA's assumption" was arbitrary); *Chemical Mfrs. Ass'n v. EPA*, 28 F.3d 1259, 1266 (D.C. Cir. 1994) (finding EPA cannot rely on general factual assertion in the face of specific contrary evidence).

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> peer review, should inform public policy. Anything less will harm decision-making that claims to protect our health.[22]

Likewise, the SAB report mentioned above questions the very basis for the proposed rule in light of the alternative methods available to validate scientific studies:

> The SAB notes that there are legitimate legal, ethical, professional and financial reasons why researchers may be unable or unwilling to fully share "data" - including statutes protecting participant privacy, experimental protocols assuring confidentiality of data for human subjects, and (for past studies) issues related to degradation and custody of data. The EPA, the U.S. Office of Management and Budget, and scientific institutions have recognized these legitimate concerns, and recognized that such constraints on availability of data do not prevent studies from being verified in other ways - or preclude those studies from being considered in regulatory decisions.[23]

This damning commentary from the scientific community itself, on a proposal that EPA has ostensibly advanced for the purpose of strengthening regulatory and influential science, merits a meaningful response from the agency. Instead, the Supplemental Notice ignores the concerns raised by the scientific community since April 2018 and proposes to dramatically expand the rule's scope. EPA's utter failure to engage these critiques underscores the proposal's arbitrariness.

C. THE SUPPLEMENTAL NOTICE FAILS TO CURE THE TOTAL LACK OF FACTUAL SUPPORT FOR THE ORIGINAL PROPOSAL.

EPA's original proposal cited seventeen sources as support for its action. As EDF thoroughly documented in its comments on the original proposal, none of these references supported the proposal. Each source cited proved to be either inapplicable, irrelevant, or contrary to EPA's proposed action.[24] Further, EPA's failure to explain its proposed departure from current agency policies and its reversal of prior agency conclusions on data availability are a hallmark of arbitrary decision-making.[25]

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[22] H. Holden Thorp et al., *Joint Statement On EPA Proposed Rule and Public Availability of Data*, SCIENCE, Dec. 6, 2019, https://science.sciencemag.org/content/366/6470/eaba3197 (emphasis added).

[23] Final SAB Report at 17.

[24] EDF 2018 Comments at 138-82; Environmental Protection Network, Comments on EPA's Proposal entitled "Strengthening Transparency in Regulatory Science," Docket ID No. EPA-HQ-OA-2018-0259-6125, at App. D (Aug. 14, 2018).

[25] *See Physicians for Soc. Responsibility v. Wheeler*, 2020 U.S. App. LEXIS 12727, at *26 (D.C. Cir. Apr. 21, 2020) ("An agency's wholesale failure to address 'past practice and formal policies regarding [an issue], let alone to explain

The Supplemental Notice drastically expands the scope of the original proposal, yet it rectifies neither its earlier citation of inapplicable, non-supportive authorities nor its failure to acknowledge or explain contradictions with current policies and prior conclusions. Nor does the Supplemental Notice cite any new authorities that support its deeply flawed approach. Although the Supplemental Notice claims that EPA's proposal is "consistent" with OMB memorandum M-19-15,[26] that memorandum says nothing about precluding the use of, or downgrading consideration given to, scientific information for which data are not publicly accessible. The memorandum in fact continues to recognize that agencies must "ensure that privacy and confidentiality are fully protected and that data are properly secure so that open data do not disclose personally identifiable information."[27] And although the memorandum discusses circumstances under which the tiered access approaches that are vaguely described in the Supplemental Notice can sometimes mitigate privacy and confidentiality concerns, the memorandum provides no support for EPA's proposal to simply ignore studies where such tiered access has not been created. As we noted in our August 2018 comments, prior OMB IQA guidance and implementing regulations make clear that studies and models are not to be *a priori* rejected or downgraded due to the mere fact that the data underlying them cannot be made public due to protections for privacy, confidential business information, or other data safeguards.[28] EPA's failure to provide adequate support for its proposed course of action is the antithesis of reasoned decision making.[29]

Not only do EPA's purported supporting authorities provide no support for the proposed rule, but there is also a plethora of evidence that EPA's existing approaches to evaluation of scientific studies, models, and other information underlying influential scientific information (ISI) are not only functioning well, but are exemplary. EPA's requirement of peer review of all ISI

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its reversal of course . . . [is] arbitrary and capricious.'") (quoting *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 927 (D.C. Cir. 2017)) (alterations in original).

[26] 85 Fed. Reg. at 15,398.

[27] Office of Mgmt. & Budget, M-19-15, Memorandum for the Heads of Executive Departments and Agencies, at 5 (Apr. 24, 2019).

[28] The OMB Guidelines recognize that data availability is not necessary to high quality science, but is one among many factors. While imposing high standards of quality, objectivity, utility, and integrity of information disseminated by Federal Agencies, the Guidelines recognize the need to implement controls "flexibly, and in a manner appropriate to the nature . . . of the information to be disseminated." Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452, 8453 (Feb. 22, 2002). As part of ensuring "objectivity," these guidelines encourage agencies that disseminate influential scientific, financial, or statistical information to "include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties." *Id.* at 8460. In particular, OMB has made clear that interest in making data publicly available "does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections." *Id.*

[29] *See, e.g.*, *AT&T v. FCC*, 86 F.3d 242, 298 (D.C. Cir. 1996) (reliance on conclusory assertion without supporting evidence is arbitrary); *Chemical Mfrs. Ass'n v. EPA*, 28 F.3d at 1266 (stubborn adherence to conclusion without supporting evidence is arbitrary); *Fred Meyer Stores, Inc. v. NLRB*, 865 F.3d 630, 639 (D.C. Cir. 2017) (similar).

assures that ISI and underlying information are rigorously examined both within and without the agency before dissemination or other utilization.[30] Furthermore, EPA's *Scientific Integrity Policy* successfully promotes use of best science by not imposing *a priori* constraints on which information is to be used, but rather by considering data on its individual merits, unconstrained by political or other interference.[31] Although the policy recognizes the importance of the ability to independently validate scientific information and methods, as well as the importance of access to data and non-proprietary models used to support agency action, these values are not absolute rules barring or downgrading consideration of legitimate data and information.[32] EPA's traditional weight-of-evidence approach to data evaluation has express judicial imprimatur, as does its decision to consider studies for which not all underlying data are publicly available for legitimate reasons.[33] EPA's failure to even acknowledge its prior policies, much less rationally explain its proposed radical deviation from them, is a fundamental legal error.[34]

D. Recent Information Only Reinforces the Arbitrariness of the Original Proposal.

Other information that has emerged since August 2018 reinforces the deficiencies that EDF highlighted in its initial comments.

Risk of Re-identification. For example, our initial comments pointed out that EPA had failed to meaningfully address concerns that even partial public disclosure of the data underlying health studies could undermine the guarantees of privacy and confidentiality that are usually provided to participants in those studies. As we documented with extensive record evidence, advances in computing have made it possible to identify participants in studies and details about their personal and medical histories, even where researchers have taken steps to mask that information or otherwise "de-identify" the data before disclosing it.[35] In July 2019, a major new study published in the journal *Nature Communications* provided a rigorous assessment that underscores these concerns.[36] Working with datasets of personal attributes drawn from the Census

[30] EPA, Peer Review Handbook, EPA/100/B-15/001, at 20-21, B-12, B-37 (4th ed. 2015).

[31] EPA, Scientific Integrity Policy 3, 5 (2012).

[32] *Id.* at 4.

[33] *Mississippi v. EPA*, 744 F.3d 1334, 1344 (D.C. Cir. 2013); *Am. Trucking Ass'n v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002); *Coal. of Battery Recyclers Ass'n v. EPA,* 604 F.3d 613, 622-23 (D.C. Cir. 2010).

[34] *Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *26.

[35] EDF 2018 Comments at 45-47.

[36] Luc Rocher, Julien M. Hendrickx & Yves-Alexandre de Montjoye, Estimating the Success of Re-Identifications in Incomplete Datasets Using Generative Models, Nature Commc'n, July 23, 2019; *see also* Gina Kolata, *Your Data Were 'Anonymized'? These Scientists Can Still Identify You,* N.Y. Times (July 23, 2019), https://www.nytimes.com/2019/07/23/health/data-privacy-protection.html.

and other sources, the authors were able to demonstrate that 99.98% of Americans could be correctly re-identified using a combination of just 15 demographic attributes.[37] As the authors state, their results "reject the claims that, first, re-identification is not a practical risk and, second, sampling or releasing partial datasets provide plausible deniability."[38] The authors further conclude that their results "question whether current de-identification practices satisfy the anonymization standards of modern data protection laws."[39]

Likewise, comments submitted by the Health Effects Institute (HEI) to the SAB in advance of the Board's August 27, 2019, teleconference on data privacy issues underscored that "depersonalized" datasets cannot be made available in a way that enables useful re-analysis of the data. As the comments note, "it is not possible to conduct a high-quality air pollution and health study without knowing the locations of those being studied, i.e. where they live, and what are the sources and levels of their air pollution exposure. . . . [O]nce that information is available at smaller spatial scale, it is possible to disclose extensive medical information for individual study subjects."[40] A member of the SAB, Dr. Richard Smith, echoed this concern in the consultation document—observing that "even de-identified data might not be sufficient to confirm the analysis" because location-specific data is essential to many environmental epidemiology studies.[41] As Dr. Smith pointed out to EPA, this is why "major datasets that include individual participant addresses (for example, the Women's Health Initiative) maintain strict rules on the confidentiality of that information. I don't see how this is going to be reversed."[42]

Finally, SAB's report on this proposal echoes these concerns, concluding that:

> Although the Proposed Rule suggests that privacy and confidentiality issues can be addressed through anonymization or de-identification, this is not always the case. The U.S. Office of Management and Budget (OMB, 2013), Health Effects Institute, National Academies of Science (NRC, 2005), and independent experts (Rothstein, 2010; Commission on Evidence-Based Policy Making, 2017; Rocher et al., 2019) have all found that even de-identified datasets present significant risks of

[37] Rocher et al., *supra* note 36, at 1.

[38] *Id.* at 2.

[39] *Id.*

[40] Letter from Daniel Greenbaum, President, HEI, to Michael Honeycutt, Chair, Science Advisory Board (Aug. 20, 2019).

[41] SAB, Consultation on Mechanisms for Secure Access to Personally Identifying Information (PII) and Confidential Business Information (CBI) Under the Proposed Rule, *Strengthening Transparency in Regulatory Science*, EPA-SAB-19-005, at B-33 (Sept. 20, 2019) ("SAB Consultation").

[42] *Id.*

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reidentification given modern techniques for combining these datasets with other sources of individual information (also known as a "mosaic effect").[43]

Risk that EPA Will Lose Access to Valuable Research, Both Past and Future. EDF's August 2018 comments also noted that EPA had utterly failed to acknowledge—much less seriously assess or consider—the possibility that its proposal would undermine scientific integrity at the agency by constricting the agency's ability to utilize valuable data and research that legitimately or ethically cannot be disclosed (even in a controlled setting, such as a tiered-access arrangement).[44] Comments submitted by Bernard Goldstein of the Environmental Protection Network for the SAB's August 2019 consultation underscore these concerns. Goldstein's comments pointed to the example of a 2010 study on the effects of formaldehyde exposure that had 34 co-authors from seven different institutions and three different countries.[45] Goldstein observed that sharing the underlying data from that study would potentially require the unanimous agreement of all 34 co-authors, many of which answer to different Institutional Review Boards that must approve such sharing, and some of whom are subject to different privacy laws than those that apply in the United States.[46] As Goldstein also observed, "international studies with or without significant U.S. collaboration are becoming an increasing percentage of total environmental health research. Isn't one of the inevitable outcomes of EPA's proposal a cumbersome barrier to being able to put together a team of international investigators for studies of humans that are potentially relevant to EPA's environmental regulations?"[47] Neither the original proposal nor the Supplemental Notice meaningfully considers this critical question and the implications that it poses for EPA's ability to consider regulatory science.

Similarly, Dr. Janice Chambers—a member of the SAB—commented in response to EPA's charge questions that even a "tiered access" approach to disclosing data would not be possible to apply retroactively to studies carried out in the past. Based on her personal experience, Dr. Chambers opined that "many of the older epidemiology studies would not have considered this option in their Informed Consent Forms" and that the researchers who conducted those studies (assuming they are even available) would therefore not have consent to share the data for reanalysis.[48] Dr. Chambers also noted that the "option of [personally identifiable information] being released to unknown people in the future would have caused some participants to decline participation," suggesting that a tiered access requirement would inhibit participation in future

[43] Final SAB Report at 11-12.

[44] EDF 2018 Comments at 67, 85-94.

[45] Bernard D. Goldstein, Presentation to the EPA Science Advisory Board 2 (Aug. 27, 2019).

[46] *Id.*

[47] *Id.* at 2-3.

[48] SAB Consultation at B-10.

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health studies and potentially damage the quantity and quality of future research that is relevant to regulatory action.[49] Dr. Kenneth Portier's comments as a member of the SAB echo this concern and note that participants in past health studies may either have died or be unable to provide consent due to age or illness—and that even participants who are reachable may be unwilling to release subsets of their data even to "safe harbor data archives."[50]

SAB's final report on the proposed rule—though it was issued after the publication of the Supplemental Notice—pointedly underscores EPA's failure to consider these central concerns. For example, SAB noted that "[i]t is not clear: (1) how many of the studies EPA currently relies upon to take important regulatory actions would meet the public disclosure standards stated in the Proposed Rule, and (2) whether EPA has assessed the feasibility of making underlying information from the studies publicly available, or what the impact of precluding those studies would be on EPA's decision making and its ability to protect public health/environment."[51] EPA thus continues to disregard the likelihood that its rule would severely erode the best available science available to the agency, which it recognizes "must serve as the foundation of [its] regulatory actions."[52] The proposal remains arbitrary in ignoring this obvious—and now expanded—counterproductive effect.[53]

Practical and Economic Impediments to Tiered Access Arrangements and Retrospective Application. As also referenced in Section V.A and .B of these comments, EPA's proposed "tiered access" approach fails to engage with or even acknowledge concerns that have been presented multiple times to the agency regarding the cost and feasibility of establishing such arrangements on a routine basis. The HEI comments to SAB noted that tiered-access arrangements, such as proposed in the Supplemental Notice, require the consent and collaboration of researchers and can be "challenging" to establish.[54] Further, Dr. Richard Smith's feedback to EPA in the SAB consultation on tiered access issues notes that the federal tiered-access models EPA has pointed to are relevant only to "a small fraction of published epidemiology research" and that these platforms do not address access to datasets held by universities or by private organizations like the American

[49] *Id.*

[50] *Id.* at B-28.

[51] SAB Final Report at 15.

[52] 83 Fed. Reg. at 18,769.

[53] *See Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *27 ("Even the Directive itself agrees that 'it is in the public interest to select the most qualified, knowledgeable, and experienced candidates.' Yet the Directive nowhere confronts the possibility that excluding grant recipients—that is, individuals who EPA has independently deemed qualified enough to receive competitive funding—from advisory committees might exclude those very candidates." (citations omitted)).

[54] Letter from Daniel Greenbaum, *supra* note 40.

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Cancer Society.[55] Dr. Smith also highlighted that federal research centers allowing tiered access require researchers to visit in person and require a federal employee to approve all outputs taken from the research center; Center for Medicare and Medicaid Services allows for remote use of data, but only after the researcher signs a contract with CMS that provides for the data to be maintained on a secure server—a process that in Dr. Smith's experience "took some months to set up and (as I understand) a considerable sum of money."[56] EPA's Supplemental Notice makes no mention of and gives no consideration to these practical impediments to tiered access.

Recent information has also underscored EPA's failure to consider the costs to researchers of demanding that older data be made available for reanalysis (either to the public or through a tiered access mechanism), and the implications that cost would have on EPA's access to regulatory science. For example, SAB member Robert W. Merritt commented in the SAB's September 2019 consultation that data from older studies may be located in obsolete storage media or data formats that are either impossible or very costly to convert to a shareable form.[57] Moreover, because the grants funding older studies have already lapsed, there would likely be little to no funding available for datasets owned by academic and non-profit institutions to be shared—meaning that much of this research would not be eligible for EPA's consideration, and that EPA might be drawing from a biased pool of for-profit industry studies.[58] Previously, EPA had accepted some responsibility for making information publicly available in a "cost-effective" way.[59] Now, it has disclaimed this role and abandoned any pretense of contributing to the transparency and validity it supposedly seeks, opting simply to discard studies out of hand.[60]

SAB's final report on the proposed rule underscores these concerns. As the SAB concluded, "the retrospective application of modern transparency standards is a challenge. A large amount of work would be required to locate, curate and retrospectively make datasets available for public access. This requirement could adversely affect the ability to move this program forward in a meaningful capacity."[61] A separate passage of the SAB report cautioned that "[a]nother aspect to consider is the practical aspect of actually conducting a reanalysis of a major epidemiological study. Such an enterprise requires an enormous amount of work even for a well-qualified

[55] SAB Consultation at B-32.

[56] *Id.*

[57] *Id.* at B-24 to -25.

[58] *Id.*

[59] 83 Fed. Reg. at 18,771 ("EPA should collaborate with other federal agencies to identify strategies to protect confidential and private information in any circumstance in which it is making information publicly available. These strategies should be cost-effective.").

[60] 85 Fed. Reg. at 15,402.

[61] Final SAB Report at 15.

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researcher. The Health Effects Institute (HEI) established a model for conducting such a reanalysis in its 2000 reanalysis of the Six Cities and American Cancer Society datasets (HEI, 2000). However, HEI has not repeated this kind of exercise."[62] EPA now clarifies that it could consider a study even if no one has independently validated it.[63] The SAB's critique, however, highlights the minimal value of public disclosure in "[e]nhancing the transparency and validity of the scientific information relied upon by EPA" to "strengthen[] the integrity of EPA's regulatory actions."[64] Because EPA has not explained how a public disclosure requirement, alone, would appreciably enhance the validity of the scientific information supporting its actions—or, on balance, strengthen their integrity—its proposal remains arbitrary.[65]

E. The New Proposed Regulatory Language in the Supplemental Notice Confirms That the Rule Would Arbitrarily Apply Retroactively.

At the time of the 2018 proposal, EPA had not clearly indicated whether it would apply the proposed rule retroactively to data and models completed or updated prior to the rule. EDF commented that *any* retroactive application of the proposed rule to models and data completed or updated prior to this rule would be both unlawful and bad policy. Unfortunately, the revised regulatory language proposed in the Supplemental Notice indicates that EPA does intend to apply the rule retroactively. First, both the tiered-access proposal and the weighting alternative proposed for inclusion in section 30.5 would apply "regardless of when the data and models were generated."[66] Second, new language in proposed section 30.9 would authorize the Administrator to exempt a study from the rule's public availability requirements if "the development of the data or model was completed or updated before" the effective date of the final rule.[67] While EPA implies that including the age of data and models as an exemption criterion would soften the rule's impact (e.g., describing older studies as being "eligible for consideration" under the proposed

[62] *Id.* at 19.

[63] 85 Fed. Reg. at 15,403 ("EPA is also clarifying that the Agency does not intend to make all data and models underlying pivotal regulatory science and pivotal science publicly available. . . . Rather, EPA is describing how it will handle studies based on whether the underlying data and models are publicly available.").

[64] 83 Fed. Reg. at 18,769.

[65] *See Physicians for Soc. Responsibility v. Wheeler*, 2020 U.S. App. LEXIS 12727, at *27 ("Even the Directive itself agrees that 'it is in the public interest to select the most qualified, knowledgeable, and experienced candidates.' Yet the Directive nowhere confronts the possibility that excluding grant recipients—that is, individuals who EPA has independently deemed qualified enough to receive competitive funding—from advisory committees might exclude those very candidates." (citation omitted)).

[66] 85 Fed. Reg. at 15,403. EPA solicits comment on "whether this [requirement] should apply only to data and models that are generated . . . after the effective date of this rulemaking." *Id.* It does not elaborate on the reasons for prospective application, nor does it propose prospective application as an alternative approach.

[67] *Id.* at 15,406.

rule's exemption provisions[68]), in reality, this new language would confirm that the rule's requirements do in fact apply to pre-existing data and studies unless the Administrator exercises his or her discretion to exempt them. EDF strongly opposes this proposed regulatory language. If EPA persists in finalizing this unlawful and arbitrary rule, EPA must expressly not apply it to data and models completed or updated prior to this rulemaking.

As discussed below and in EDF's 2018 comments, EPA has not demonstrated—and cannot demonstrate—that a study cannot be scientifically valid unless the underlying data and models are publicly disclosed. And, while scientists might be aware of the rule's public disclosure requirements in the future, such requirements did not apply in the past, and it often will not be possible to make data and models underlying older studies publicly available.[69] EDF's 2018 comments provided many reasons why data and models from past research might not be available (or amenable to tiered access), including data loss over time, multiple owners of data, and inability to obtain participant consent.[70] In fact, EPA acknowledges in the Supplemental Notice that "[t]he underlying data, models and computer code for some studies, particularly older studies, may not be readily publicly available because of the technological barriers to data and model sharing (e.g., differences in data storage devices or data retention practices) that existed when they were developed."[71] Thus, applying the rule retroactively would result in excluding valid and reliable studies from EPA's consideration when promulgating rules and adopting policies.[72] And even where it is technically possible to comply with the proposed public disclosure requirements, such disclosure would be prohibitively expensive and time-consuming. As the SAB explains, "[a] large amount of work would be required to locate, curate and retrospectively make datasets available for public access."[73] Thus, it is unrealistic to expect that a significant number of older studies will be reviewed and brought into compliance with the proposed data and disclosure requirements.

Incentivizing scientists to make the data and models underlying their studies publicly available where it is lawful, feasible, and ethical to do so is a worthwhile goal, to the limited extent

[68] *Id.* at 15,403.

[69] *See* Final SAB Report at 15 ("[I]t will not always be possible to apply these same standards retrospectively.").

[70] EDF 2018 Comments at 38-39. The possibility that the Administrator would grant an exemption, on a case-by-case basis, because of the age of the data, 85 Fed. Reg. at 15,403, does not remove the presumption that EPA will ignore or downgrade valid historical studies.

[71] 85 Fed. Reg. at 15,403.

[72] EDF's 2018 comments identify several studies that likely would be eliminated from EPA's consideration if this rule were finalized—or at least downgraded in importance—despite the fact that each has been validated using approaches that did not require public disclosure of underlying data and models. EDF 2018 Comments at 58, 70-75; *see also* Harvard Law School Emmett Environmental Law & Policy Clinic, Comments on Proposed Rule, Strengthening Transparency in Regulatory Science, Docket ID No. EPA-HQ-OA-2018-0259-6111, at 9-12 and Att. 1 (Aug. 7, 2018).

[73] Final SAB Report at 15.

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that it improves the reliability of the science the agency relies on to fulfill its statutory duties. But doing so in a way that prevents EPA from considering (or allows EPA to ignore) otherwise valid and reliable studies when formulating rules and policies is plainly unlawful. And applying that approach retroactively to studies for which public disclosure of underlying data and models is impracticable, if not impossible, fails even to achieve the goal of marginally improving the quality of the science on which the agency relies. As explained in the Final SAB Report on this rulemaking, "retrospective application of the requirement would be difficult to implement, could be expensive with no clear responsibility regarding who would cover the added cost, and could arbitrarily impact the conclusions drawn."[74] In sum, retroactive application of the proposed rule would only serve to unlawfully eliminate or impair EPA's ability to consider valid, relevant science when seeking to fulfill its mission of protecting public health and the environment. EDF opposes this misguided and unlawful proposal in its entirety, but if EPA does move forward with finalizing it, EPA must eliminate the proposed regulatory language indicating that the rule applies retroactively. Instead, EPA must confirm in section 30.5 that there will be no retroactive application of the rule.

II. EPA DOES NOT HAVE AUTHORITY TO ISSUE THE PROPOSED RULE AND THE SUPPLEMENTAL NOTICE FAILS TO REMEDY THIS DEFECT

The Supplemental Notice fails to identify any viable additional sources of authority for the 2018 Proposal. None of the discussed authorities under the Federal Housekeeping Act, referenced environmental statutes, or the Information Quality Act support the 2018 proposal or rectify its numerous statutory violations identified in previous comments. Since "an agency literally has no power to act . . . unless and until Congress confers power upon it," the 2018 proposal must be withdrawn for a lack of statutory authority.[75]

A. THE FEDERAL HOUSEKEEPING ACT PROVIDES NO AUTHORIZATION FOR EPA'S PROPOSED REGULATION.

In the Supplemental Notice, EPA asserts that an obscure federal law known as the "Housekeeping Act" authorizes its sweeping attack on health science. This novel legal theory flouts the plain language and history of this statute, both of which make clear that EPA is not an "executive department" with the associated authorities under this statute. Equally important, even if EPA *were* an executive department, the 2018 proposal is clearly substantive and has "binding effects" on the public and the agency itself, which profoundly influence EPA's implementation of multiple environmental laws and capacity to protect public health and the environment. It is black

[74] *Id.* at 17.

[75] *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986).

letter law that the Housekeeping Act cannot be used to authorize such substantive rules. The proposal is therefore beyond the housekeeping powers granted by the statute for *any* agency.

1. EPA Is Not an "Executive Department" Under the Housekeeping Act.

EPA's attempt to rely on the Housekeeping Act[76] as a source of authority directly contradicts the statute's explicit allocation of these housekeeping authorities to "Executive departments"—which EPA is not. The statute provides that "the head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property."[77] By its terms, this statute authorizes an executive department "to regulate its own affairs" through "rules of agency organization procedure or practice."[78]

EPA is not an "Executive department" within the meaning of section 301. As EPA acknowledges in the Supplemental Notice, section 101 of Title 5 explicitly lists the fifteen entities considered "Executive departments" under section 301,[79] and EPA is not among them.[80] The statute instead designates EPA as an "independent establishment," under section 104. Section 104 defines an "independent establishment" as "an establishment in the executive branch . . . which is not an Executive department, military department, Government corporation, or part thereof, or part of an independent establishment."[81] Since EPA is an "independent establishment" rather than an "Executive department," the agency cannot rely on section 301 as the source of its authority for the 2018 Proposal.[82]

[76] 5 U.S.C. § 301.

[77] *Id.*

[78] *Chrysler Corp. v. Brown*, 441 U.S. 281, 309-10 (1979).

[79] Section 101 lists 15 executive departments (which are the 15 cabinet-level departments): the Department of State, the Department of the Treasury, the Department of Defense, the Department of Justice, the Department of the Interior, the Department of Agriculture, the Department of Commerce, the Department of Labor, the Department of Health and Human Services, the Department of Housing and Urban Development, the Department of Transportation, the Department of Energy, the Department of Education, the Department of Veterans Affairs, and the Department of Homeland Security.

[80] 5 U.S.C. § 101; 85 Fed. Reg. at 15,397 ("EPA is not one of the 15 'Executive Departments' listed at 5 U.S.C. 101.").

[81] 5 U.S.C. § 104.

[82] *See also* William Funk, *Is the Environmental Appeals Board Unconstitutional or Unlawful?*, 49 Envtl. L. 737, 742-43 (2019) (stating that EPA is not an executive department under the Housekeeping Act so was not authorized to issue a proposal under section 301).

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EPA incorrectly asserts that EPA has gained the authorities of an "Executive department" through delegation and reorganization. In the Supplemental Notice, EPA claims that Reorganization Plan No. 3, which established EPA—and contains no mention of the Housekeeping Act—implicitly granted EPA this status when it transferred programs and authorities from the Departments of Interior and Health, Education, and Welfare to the newly formed EPA.[83] Admitting that nothing in Reorganization Plan No. 3 explicitly grants this authority, EPA points to a 2008 OLC opinion, on the entirely unrelated topic of whether federal employees should be held responsible for lost or damaged federal property, which contends that section 2(a)(9) of the plan implicitly confers this authority alongside the explicit transfer of various functions.[84]

Such a strained interpretation clearly contradicts the requirement for Congress to amend the statute, if it so wills, to recognize additional executive departments. Congress has demonstrated its capacity to grant newly created government entities the status of executive departments with housekeeping authorities when it so chooses. In 2002, Congress created the Department of Homeland Security and, similar to EPA's Reorganization Plan No. 3, laid out the functions transferred from existing departments to the new department. In section 101 of the Homeland Security Act, Congress specifically provided that the Department of Homeland Security was being "established . . . as an executive department of the United States within the meaning of title 5."[85] Congress has had decades to take equivalent action with regard to EPA, and Congress's choice to not update the "Executive department" list cannot be conveniently ignored. To this day, EPA remains an "independent establishment" under the Housekeeping Act. It defies any reasonable interpretation for EPA to be simultaneously designated as an "executive department" and an "independent establishment," when the latter is defined as an entity not listed among the former. To construe EPA as an "executive department" contradicts the plain language of the statute and congressional intent.

EPA attempts to skirt around this glaring omission by scraping together two cases in which it claims courts recognized EPA to have section 301 housekeeping authority. The first case EPA cites for support, *EPA* v. *General Electric Co.*,[86] concerns the judicial reviewability of EPA's refusal to comply with a third-party subpoena under the APA. The court found the refusal reviewable;[87] it did not find that EPA's regulations, which claimed section 301 among other

[83] *See* Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970).

[84] *See Authority of the Environmental Protection Agency to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Government Personal Property*, 32 Op. O.L.C. 79 (2008).

[85] 6 U.S.C. § 111(a).

[86] 197 F.3d 592 (2d Cir. 1999); *see also* 85 Fed. Reg. at 15,397.

[87] *Gen. Elec. Co.*, 197 F.3d at 598-99.

authorities, applied to the subpoena as issued. The court referenced EPA's potential housekeeping authority only in dicta without any further discussion or analysis.[88]

In the second case EPA references for support, *Boron Oil Co.* v. *Downie*,[89] the court held that the lower courts lacked jurisdiction to compel an EPA employee to appear and testify in a state court action to which the government is not a party as EPA was protected by sovereign immunity.[90] While finding the grant of sovereign immunity sufficient on its own merit, the court explained that the principle of federal supremacy supports the protection of sovereign immunity such that the state court could not compel testimony in violation of EPA's housekeeping regulations.[91] But the court provided no explication of how EPA could be construed as an "Executive department" under the Housekeeping Act with relevant authority to issue such regulations. Moreover, the EPA regulations there in question claim an assortment of authorities, not only the Housekeeping Act.[92]

The Supplemental Notice also broadly cites *Chrysler Corp. v. Brown*.[93] But that case provides no additional basis to apply section 301 authority to an "independent establishment," as the case concerns the Department of Labor—a listed executive department under the Housekeeping Act. It also holds that the Housekeeping Act does not authorize issuance of substantive rules, as discussed *infra*.

None of the cited cases hold that EPA is an executive department under the Act. As EDF has argued in other contexts, EPA undoubtedly has administrative authority to undertake its statutory obligations. This comment argues only that section 301 is not the source of that authority. However, even if EPA were to be recognized to have section 301 authority, section 301 does not provide authority for *any* executive department to issue a substantive rule such as the Supplemental Notice.

2. The Housekeeping Act Does Not Authorize Substantive Rules.

In the primary case EPA cites for its alleged authority under the Housekeeping Act to issue the proposal, *Chrysler Corp. v. Brown*, the Supreme Court makes explicit that the Housekeeping Act cannot authorize substantive rules such as the current proposal. *Chrysler Corp.* concerned a

[88] *Id.* at 595-97.

[89] 873 F.2d 67 (4th Cir. 1989); *see also* 85 Fed. Reg. at 15,397.

[90] *Boron Oil Co.*, 873 F.2d at 70.

[91] *Id.* at 71.

[92] *Id.* at 69; *see also* 40 C.F.R. § 2.401(c).

[93] 441 U.S. 281 (1979); *see also* 85 Fed. Reg. at 15,397.

government contractor who asked the court to enjoin release of documents regarding petitioner's employment practices. The documents had been requested under FOIA, and a division of the Department of Labor had determined they should be released, consistent with FOIA and disclosure regulations from the Department of Labor's Office of Federal Contract Compliance Programs (OFCCP). The court concluded that section 301 did not authorize the OFCCP regulations, explaining that section 301 is a "housekeeping statute," authorizing only rules of agency organization, procedure, or practice as opposed to "substantive rules."[94] It found "nothing in the legislative history of § 301 to indicate it is a substantive grant of legislative power to promulgate rules authorizing the release of trade secrets or confidential business information."[95] The case offers no support for a more expansive reading of what constitutes non-substantive rules of agency organization, procedure, or practice for even an executive department—which, as explained above, EPA is not.

Congress took explicit action in 1958 to amend section 301 to "correct" agencies from abusing the Housekeeping Act by attempting to use its authority as a substantive basis to withhold information from the public.[96] The Supreme Court noted in *Chrysler Corp.* "that Congress had looked carefully at the statute in 1958; that the Special Subcommittee on Government Information had 'unanimously agreed that [§ 301] originally was adopted in 1789 to provide for the day-to-day office housekeeping in the Government departments,' and that attempts to construe it as something more was 'misuse' which 'twisted' the statute."[97] The courts have repeatedly checked subsequent agency attempts to "twist" the statute to a range of substantive purposes and found those efforts illegal, including halting government's extralegal efforts to limit disclosure and inclusion of information in the scientific process [98] The Supplemental Notice now attempts to similarly and

[94] *Chrysler Corp.*, 444 U.S. at 310.

[95] *Id*. (emphasis omitted); *see also United States ex rel. O'Keefe v. McDonnell Douglas Corp.*, 132 F.3d 1252, 1255 (8th Cir. 1998) (applying *Chrysler Corp.* and finding that the housekeeping statute did not provide authority for substantive regulations).

[96] H.R. No. 1461, 85th Cong., 2d Sess. (1958), *reprinted in* 1958 U.S.C.C.A.N. 3352, 3353.

[97] *U.S. ex rel. O'Keefe*, 132 F.3d at 1255 (quoting *Chrysler Corp.*, 441 U.S. at 310 n.41).

[98] *See City & Cty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001, 1023 (N.D. Cal. 2019) (vacating regulations from the Department of Health and Human Services and explaining that defendants "mistakenly rely on their 'housekeeping authority' to support their authority to promulgate the rule" but "[n]one of the statutes cited by defendants provide HHS with the authority to promulgate substantive rules" including the Housekeeping Act); *United States ex rel. O'Keefe*, 132 F.3d at 1255 ("In recent years, several agencies have unsuccessfully attempted to find statutory authority for substantive regulations in the Housekeeping Statute."); *In re Bankers Trust Co.*, 61 F.3d 465, 470 (6th Cir. 1995) (holding regulation requiring subpoenaed party to refuse production of confidential information was not authorized by the Housekeeping Statute and "exceeded the congressional delegation of authority"), *cert. dismissed*, 517 U.S. 1205 (1996); *Exxon Shipping Co. v. United States Dep't of Interior*, 34 F.3d 774, 776-78 (9th Cir. 1994) (holding that the Housekeeping Act did not authorize regulations allowing agency to withhold deposition testimony of federal employees); *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 826-27 (S.D. Ohio 1995) (holding that the Housekeeping Act did not authorize a 1953 Defense Department directive on the use of human volunteers in

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illegally twist the statute to withhold science from consideration in rulemakings that broadly affect the public interest.

3. The Proposal Is a Substantive Rule and Hence Not Authorized by the Housekeeping Act.

The 2018 proposal and Supplemental Notice meet the court-determined criteria for a substantive regulation, refuting EPA's claim that it is proposing merely an "internal rule of agency procedure."[99] A "substantive rule" is not defined in the APA, but in distinguishing between "substantive rules" and "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice," courts have described "substantive rules" as those "affecting individual rights and obligations," a quality which helps identify which rules are "binding" or "have the force of law."[100] By contrast, courts have held that regulations issued pursuant to the authority under the Housekeeping Act "do not have the force and effect of law,"[101] and are "directory, not mandatory in nature."[102] Courts have not been shy in finding executive departments' regulations to be substantive rules exceeding authorities under the Housekeeping Act.[103]

In *CropLife Am. v. EPA*,[104] the D.C. Circuit Court of Appeals considered whether an EPA press release, which stated that the agency would not consider third-party-controlled human exposure studies for purposes of pesticide registration subject to case-by-case consideration of individual studies, was a substantive rule. The court held that the press release bound both EPA and registrants during pesticide registrations and so was a binding "substantive rule."[105] In reaching its decision, the court considered two established case law formulations for determining

experimental research); *McElya v. Sterling Med. Inc.*, 129 F.R.D. 510, 514 (W.D. Tenn. 1990) (concluding that the Housekeeping Act did not give the Department of Navy authority to create general discovery privilege for persons under its jurisdiction).

[99] 85 Fed. Reg. at 15,398.

[100] *Chrysler Corp.*, 441 U.S. at 301-302 (quoting *Morton* v. *Ruiz*, 415 U.S. 199, 232, 235-236 (1974)).

[101] *See, e.g.*, *Einhorn v. DeWitt*, 618 F.2d 347, 350 (5th Cir. 1980) (reviewing regulations arising from the Internal Revenue Service's Statement of Procedural Rules promulgated under 5 U.S.C. §§ 301, 552 and finding that "[t]heir purpose is to govern the internal affairs of the Internal Revenue Service. They do not have the force and effect of law.").

[102] *Boulez v. Comm'r*, 810 F.2d 209, 215 (D.C. Cir. 1987).

[103] *See supra* note 98.

[104] 329 F.3d 876 (D.C. Cir. 2003).

[105] *Id.* at 883.

whether an agency action constitutes a substantive regulation: the effects of the agency's action;[106] and the agency's expressed intentions regarding the action.[107] Consistent with *Chrysler Corp.*, the two analyses overlap in recognizing that a substantive action "binds private parties or the agency itself with the 'force of law.'"[108] In *Croplife*, the court determined: "EPA's stated rule is binding on petitioners, who are now barred from relying on third-party human studies (even in cases where such studies formerly were approved), and is binding on the agency because EPA has made it clear that it simply 'will not consider' human studies."[109]

Like the action at issue in *Croplife*, both the original proposal and the Supplemental Notice would bind EPA to not consider or to discount a scientific study it could have previously given full consideration, all else being equal, if the study fails to meet the new requirement that underlying data and models be publicly available (or available through tiered access). The only possible exception would be if an otherwise disqualified study met the proposal's exemption criteria and the Administrator exercised his or her discretion to grant an exemption. Likewise, the proposed rule would bind the public, including organizations such as EDF, who can no longer receive the benefit of EPA's full consideration of valid but non-complying studies that they submit to the agency as part of an administrative record for an agency action, which EPA would previously have been required to consider as part of the rulemaking process. Furthermore, EPA's rule would require researchers interested in contributing to regulatory protections and influential scientific information to alter their conduct or risk having their efforts deemed unusable. Ultimately, the rule would diminish the public's statutorily protected interests in regulations informed by the best available science, an outcome that results from substantive choices about the scientific evidence it will consider.[110]

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[106] *See Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) (quoting *Am. Bus Ass'n v. United States*, 627 F.2d 525, 529 (D.C. Cir. 1980)) (considering whether the agency action (1) "impose[s] any rights and obligations," or (2) "genuinely leaves the agency and its decisionmakers free to exercise discretion").

[107] *See Molycorp, Inc. v. EPA*, 197 F.3d 543, 545 (D.C. Cir. 1999) (stating that the court considers "(1) the Agency's own characterization of the action; (2) whether the action was published in the Federal Register or the Code of Federal Regulations; and (3) whether the action has binding effects on private parties or on the agency").

[108] *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 382 (D.C. Cir. 2002); *see also Natural Resources Defense Council v. Wheeler*, 955 F.3d 68, 83 (D.C. Cir. 2020) ("A legislative rule is one that has legal effect or, alternately, one that an agency promulgates with the intent to exercise its delegated legislative power by speaking with the force of law. . . . Here, the 2018 Rule has independent legal effect beyond that compelled by *Mexichem* and reflects EPA's intent to exercise its delegated legislative power." (internal citation and quotation marks omitted)).

[109] *Croplife*, 329 F.3d at 881.

[110] EPA itself has recently argued as much. *See* Brief for Appellees at 19, *Union of Concerned Scientists v. Wheeler*, No. 19-1383 (1st Cir. filed Oct. 7, 2019) (describing EPA's policy of disqualifying any researcher who has accepted funding from EPA from serving on a scientific advisory committee, because of concerns about the appearance of conflicts of interest, as a "substantive choice[] concerning [EPA's] advisers").

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When evaluating additional factors courts use to distinguish substantive rules, the proposal identifies itself even more definitively as a substantive rule than the EPA action reviewed in *Croplife*. First, both the 2018 proposal and the Supplemental Notice were published according to notice-and-comment procedures in the Federal Register, unlike the EPA action evaluated in *Croplife*. Courts have considered whether the agency used full public notice-and-comment procedures, which an agency need not use when producing an "interpretive" rule or rule of agency procedure, as an indicator of a substantive rule.[111] While courts consider an agency's own characterization of its action, they disregard claims that conflict with the record such as EPA's contention here that the 2018 proposal as supplemented "would not regulate the conduct or determine the rights of any entity outside the federal government."[112] "The agency's characterization of its own action is not controlling if it self-servingly disclaims any intention to create a rule with the "force of law," but the record indicates otherwise."[113] And instead of a paragraph in a mere press release, EPA proposes to publish in the Code of Federal Regulations criteria for barring studies from both regulatory and non-regulatory use—a hallmark of a substantive regulation.[114] EPA's choice to put the rule through notice-and-comment rulemaking provides further evidence that EPA regards the rule as substantive. Lastly, EPA's consideration of individual exceptions to its proposed general principle is as unavailing here as it was in *CropLife*.

Argued in the inverse, the 2018 proposal and Supplemental Notice do not meet the requirements for a rule of agency organization, procedure, or practice, for purposes of the APA. Agency actions in this category are the opposite of substantive rules; they are those "that do not themselves alter the rights or interests of parties, although [they] may alter the manner in which the parties present themselves or their viewpoints to the agency."[115] An agency action that "trenches on substantial private rights and interests" cannot be a rule of agency organization, procedure, or practice.[116] A federal court recently vacated substantive regulations issued by the Department of Health and Human Services under their "mistaken[]" claim of authority under the Housekeeping Act, finding that "[t]he challenged rule is not . . . a mere housekeeping rule. The expansive definitions in the rule depart from the federal statutes, as explained above, changing the rights and responsibilities of health care providers."[117]

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[111] *See, e.g.*, *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 172–73 (2007); *see also* 5 U.S.C. § 553(b)(3)(A); *Molycorp*, 197 F.3d at 545.

[112] 85 Fed. Reg. at 15,398.

[113] *Croplife*, 329 F.3d at 883 (citing *Gen. Elec. Co.*, 290 F.3d at 383-85); *see also, e.g.*, *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 95-96 (D.C. Cir. 2002).

[114] *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 19 (D.C. Cir. 2019); *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993).

[115] *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980).

[116] *Id.* at 708.

[117] *City & Cty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001, 1023 (N.D. Cal. 2019).

By the same framework, the 2018 proposal and Supplemental Notice must be a substantive rule, exceeding the powers of the Housekeeping Act, because they affect private rights and interests. By restricting the scientific studies on which EPA may base final significant regulatory actions, EPA severely limits parties from relying on excluded studies in advocating for particular safeguards, or petitioning the agency to take a specific action, as the statute authorizes them to do. As noted in EDF's prior comments, because the rule would substantively impact agency conclusions and regulations, it impacts private rights and interests. The proposal does not allow private individuals to submit for consideration (or renders such submittal a nullity) studies that they would have been permitted to prior to the proposal, thus impacting the substantive standards that EPA is able to justify setting—which has implications for the regulated community as well as for public health.[118] EPA's proposed action "encodes a substantive value judgment [and] puts a stamp of approval or disapproval on a given type of behavior" by requiring regulatory actions to be supported only by certain scientific information deemed acceptable by the proposal.[119]

EPA has even acknowledged that the "the bulk of the responsibility for instituting new methods for access to data and models" will "fall[] on outside parties"—including both researchers and the Centers for Disease Control—according to a memorandum prepared by committee staff to capture recent briefings on the rule before the House Committee on Science, Space, and Technology.[120] For example, the memorandum records EPA's opinion that researchers, "would be responsible for managing the logistics of making the data and models publicly available in a manner that complies with the rule, in consultation with EPA staff," and the Centers for Disease Control would shoulder the burden of "hosting the data and models on its own servers, with CDC personnel working at the secure data enclave reviewing research proposals submitted by members of the public seeking to conduct their own analyses of study data and determining the level of

[118] *See, e.g.*, Comments of 88 Environmental, Farmworker, Environmental Justice, Public Health, and Animal Protection Organizations on Proposed Regulations on "Transparency" in Regulatory Science, Docket ID No. EPA-HQ-OA-2018-0259-6137, at 6-14 (Aug. 15, 2018) ("Earthjustice 2018 Comments") (discussing the substantial impacts on public health that could result from the rule as originally proposed). The public health impacts would be even greater under the expanded scope of the Supplemental Notice.

[119] *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987); *see also Pharm. Mfrs. Ass'n v. Finch*, 307 F. Supp. 858, 865 (D. Del. 1970) (finding that a regulation promulgating new criteria for clinical investigations that will meet the standards of evidence necessary to demonstrate the effectiveness of drug products, and excluding certain kinds of clinical investigations, was not merely a procedural rule, because it "did effect a material narrowing of the range of evidence which previously had been considered relevant in evaluating a drug's efficacy," "[b]ecause of the important clarification of acceptable testing standards effected by the . . . regulations," and "because of the substantial impact of the[] regulations on the drug industry. . . . ").

[120] Memorandum from Democratic Staff, H.R. Committee on Science, Space, and Technology, to Chairwoman Johnson, Re: Summary of Staff-Level Briefings from the Environmental Protection Agency on the "Strengthening Transparency in Regulatory Science" Supplemental Proposed Rule, at 2 (Apr. 30, 2020) ("Memo to Chairwoman Johnson").

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access to grant on a case-by-case basis."[121] These substantial impacts on parties outside of EPA further confirm that the proposal is not an internal or procedural rule, but a substantive rule which cannot be issued under the Housekeeping Act.

The 2018 proposal and Supplemental Notice clearly meet the criteria for a substantive rule and cannot be disguised as a procedural rule through EPA's feeble whitewashing. The Supplemental Notice expands the scope of affected regulations, thereby increasing the extent to which private rights are affected and the impacts on public health and the environment. The 2018 proposal and Supplemental Notice would have direct and appreciable legal consequences that have immediate and pervasive impacts on the information that private individuals can submit for consideration in rulemakings, and on EPA's ability to justify setting substantive standards that comply with statutory requirements specifying how to use science to protect public health and the environment.[122] In *Croplife*, the court found that a rule preventing petitioners' submission of third-party human studies to rulemakings did concretely injure the petitioners by precluding the agencies' consideration of studies that petitioners had previously been able to submit. EPA's action to prohibit consideration of any third-party studies presented a "purely legal question that does not depend upon consideration . . . particularized facts"[123] or the subsequent implementation of the rule.

B. THE HOUSEKEEPING ACT CANNOT AUTHORIZE VIOLATIONS OF OTHER STATUTES.

The Housekeeping Act provides no basis to violate other statutes, including landmark environmental laws and the Information Quality Act. As discussed above, the Housekeeping Act authorizes only procedural rules regarding "the custody, use, and preservation of [agency] records, papers, and property,"[124] as opposed to "substantive rules." Regulations issued under the Housekeeping Act "do not have the force and effect of law,"[125] and have been "held to be directory,

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[121] *Id.*

[122] *See Natural Resources Defense Council*, 955 F.3d at 90 (stating that a rule is final when it has "an immediate and practical" impact on rights and obligations).

[123] *Croplife*, 329 F.3d at 885 (quoting *Mountain States Tel. & Tel. Co. v. FCC*, 939 F.2d 1035, 1041 (D.C. Cir. 1991)) (internal quotation marks omitted).

[124] 5 U.S.C. § 301.

[125] *See Einhorn*, 618 F.2d at 350 (reviewing regulations arising from the Internal Revenue Service's Statement of Procedural Rules promulgated under 5 U.S.C. §§ 301, 552 and finding that "[t]heir purpose is to govern the internal affairs of the Internal Revenue Service. They do not have the force and effect of law." (citations omitted)); *see also* James F. Ponsoldt, *Balancing Government Efficiency and the Protection of Individual Liberties: An Analysis of the Conflict Between Executive Branch "Housekeeping" Regulations and Criminal Defendants' Rights to a Constitutionally Fair Trial*, 19 Harv. C.R.-C.L. L. Rev. 349, 370 (1984) ("The Housekeeping Statute only authorizes

not mandatory in nature."[126] While an agency is bound to adhere to all the laws it is required to administer, it is particularly egregious that EPA claims that a procedural housekeeping rule, which lacks legal force, would somehow supersede other binding statutory authorities and allow EPA to rewrite bedrock environmental statutes. The 2018 proposal and Supplemental Notice would require EPA to weigh the extra-statutory factor of data availability and disregard other high-quality data which EPA is required to review under the scientific standards of multiple environmental statutes.[127] The courts have barred previous unlawful efforts to amend binding statutory and regulatory requirements via the Housekeeping Act. Treasury Department rules derived under the Housekeeping Act were found explicitly unable to "override" other binding Treasury Department regulations promulgated pursuant to specific statutory delegation.[128] Similar logic was at work in *Chrysler Corp*. Concluding that section 301 did not authorize regulations limiting the scope of the Trade Secrets Act, the Supreme Court found the "greatest significance" to be "the 'housekeeping' nature of § 301 itself."[129]

As discussed above, EPA has styled the 2018 proposal and Supplemental Notice as a substantive rule that would bind the agency from considering scientific studies without publicly available datasets during rulemakings. However, even if the proposal was found to be validly issued under the Housekeeping Act, it could not in any way authorize violating environmental statutes or binding regulations implementing these statutes. Like the Trade Secrets Act, the major environmental statutes are binding authorities that cannot be limited by the regulations issued under the Housekeeping Act. Nor can the Housekeeping Act authorize rules that would supersede implementing regulations for environmental statutes which have been issued by specific statutory delegation in the same manner as the Treasury Department regulations discussed above.

C. NONE OF THE ENVIRONMENTAL STATUTES ORIGINALLY CITED AUTHORIZE EPA'S PROPOSED RULE OR ITS EXPANSION THROUGH THE SUPPLEMENTAL NOTICE.

As EDF explained in its comments on the 2018 proposal, none of the environmental statutes EPA identifies in the original proposal authorize EPA to issue the proposed rule or otherwise promulgate a one-size-fits-all regulation governing how the agency will consider science

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regulations consistent with law. In fact, regulations promulgated pursuant to the statute which relate to the internal operations of an agency have been held not to have the force of law even with respect to the rights of third parties.").

[126] *Boulez*, 810 F.2d at 215.

[127] For a more detailed explanation of how the 2018 proposal would violate EPA's statutory requirements under a range of environmental laws, *see* EDF 2018 Comments at 13-34 *and* Earthjustice 2018 Comments at 33-53.

[128] *Flynn v. Comm'r*, 269 F.3d 1064, 1072 (D.C. Cir. 2001).

[129] *Chrysler Corp.*, 441 U.S. at 311-12.

under its various statutory authorities.[130] EPA gives no explanation of how *any* of the provisions it cites provide authority for the 2018 proposal and Supplemental Notice, much less how all of them authorize identical requirements despite their varied obligations for considering science. Not only is there still no authority for EPA's pan-statutory proposal, but the 2018 proposal as supplemented would force EPA to more broadly violate a diversity of obligations to consider science under the different environmental laws.[131] While the specifics of the requirements vary, Congress has often commanded EPA to utilize the "best available science" for its policies, which necessitates consideration of the full range of available science. The proposal would restrict consideration of science and cause EPA to violate both its general statutory obligations to consider all available data when undertaking rulemakings as well as the specific requirements to consider science under the respective environmental statutes.[132]

The Supplemental Notice multiplies this defect, broadly expanding the regulation to cover "data and models underlying pivotal regulatory science and pivotal science used to support significant regulatory decisions and influential scientific information, respectively, not simply dose-response data and dose-response models"—effectively hamstringing the agency from considering the best available science across its full portfolio of actions to protect the environment and public health, and impeding its ability to gain a better understanding of the threats to public health and the environment.[133] Nothing in the Supplemental Notice remedies this expansive defect or even attempts to reduce it. The Supplemental Notice adds a reference to the Clean Water Act (CWA), and amends its references to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and Resource Conservation and Recovery Act (RCRA),[134] but these additions provide no additional support or authorization for the proposal.

The references to CWA and CERCLA cite to the general authorities of the EPA Administrator to issue regulations to fulfill the respective requirements of the statutes. These authorities cannot authorize the proposal's efforts to violate those statutes or act beyond the scope of their requirements.[135] Similarly, the cited provision of RCRA contains the Administrator's general authorities to promote research and training, offering no basis for the proposal's

[130] EDF 2018 Comments at 13-14; *see also* Earthjustice 2018 Comments at 18-31.

[131] *See supra* note 127.

[132] *Id*.

[133] 85 Fed. Reg. at 15,401.

[134] 85 Fed. Reg. at 15,397.

[135] *See Chrysler Corp.*, 441 U.S. at 302 ("The legislative power of the United States is vested in the Congress, and the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes."). For discussion of how the 2018 proposal exceeds the authorities of these statutes and violates the requirements of these statutes, *see* Earthjustice 2018 Comments at 26-27, 48 (CERCLA), *and id.* at 24-25, 45-47 (CWA).

requirements or reconciliation of where it may conflict with RCRA's obligations—even requirements in the very same subsection it presumes to cite for authority.[136]

D. OMB'S 2019 MEMO PROVIDES NO ADDITIONAL AUTHORITY FOR THE PROPOSAL TO VIOLATE STATUTORY OBLIGATIONS, NOR REMEDIES THE PROPOSAL'S VIOLATION OF THE INFORMATION QUALITY ACT.

As noted above, EPA claims the Supplemental Notice has been issued, at least in part, "to ensure consistency with" a memorandum issued in April 2019 by the White House's Office of Management and Budget (OMB) intended to update implementation of the Information Quality Act ("2019 OMB Memo").[137] This non-binding policy statement provides no legal authority for the proposal's numerous substantive violations of environmental statutes. Further, the Supplemental Notice and its citation to the non-binding 2019 OMB Memo fail to remedy the proposal's violation of the Information Quality Act and OMB's binding 2002 guidance on the Information Quality Act ("2002 Guidelines")[138] appropriately established through notice-and-comment rulemaking.[139]

As discussed in EDF's comments on the 2018 proposal, by prohibiting EPA from relying on a study to support a significant rulemaking if that study's underlying data and models are not publicly available, EPA's proposed rule departs from OMB's unambiguous language in its 2002 Guidelines. Specifically, EDF explained that though the 2002 Guidelines seek to ensure objectivity and transparency by encouraging agencies to make data and methods publicly available to facilitate reproducibility, they explicitly state that "agency guidelines *shall not* require that all disseminated data be subjected to a reproducibility requirement."[140] Rather, the 2002 Guidelines instruct that data shall only be subjected to a reproducibility requirement if practicable "given ethical, feasibility, or confidentiality constraints."[141] The 2002 Guidelines emphatically declare that "the objectivity standard does not override other compelling interests such as privacy . . . and other

[136] *See* Earthjustice 2018 Comments at 53.

[137] 85 Fed. Reg. at 15,398 (citing OMB, Memorandum for the Heads of Executive Departments and Agencies, Re: Improving Implementation of the Information Quality Act, M–19–15 (Apr. 24, 2019), https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf).

[138] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, 67 Fed. Reg. 8451 (Feb. 22, 2002).

[139] *Prime Time Int'l Co. v. Vilsack*, 599 F.3d 678, 685 (D.C. Cir. 2010) ("[B]ecause Congress delegated to OMB authority to develop binding guidelines implementing the IQA, we defer to OMB's reasonable construction of the statute."). EPA's publication of the 2002 Guidelines through notice-and-comment rulemaking, as required by the APA for substantive and binding rules, helps distinguish it from the 2019 OMB Memo.

[140] 67 Fed. Reg. at 8460 (emphasis added).

[141] *Id.*

confidentiality protections."[142] Nothing in EPA's Supplemental Notice remedies the 2018 proposal's violation of the Information Quality Act and OMB's binding 2002 Guidelines.

The Supplemental Notice cannot overcome these violations through reference to the 2019 OMB Memo. The 2019 OMB Memo did not replace OMB's original 2002 Guidelines and did not change the requirement that agencies require disclosure of a study's underlying data only where practicable in light of "ethical, feasibility, or confidentiality constraints."[143] Nor could it. Even though the 2019 OMB Memo is intended to update the 2002 Guidelines, the memo is merely a non-binding policy statement sent to the heads of executive departments,[144] whereas OMB issued the 2002 Guidelines as a binding rule through the required notice-and-comment rulemaking process.[145]

Even absent the clear legal precedence of the 2002 Guidelines, the 2019 OMB Memo lacks the mandate that EPA seeks to support its 2018 proposal. The 2019 OMB Memo is clear that the updated expectations regarding public accessibility and reproducibility do not compel public disclosure of underlying data. First, though the 2019 OMB Memo recommends that agencies "prioritize increased access to the data and analytic frameworks (e.g., models) used to generate influential information,"[146] nowhere does it authorize agencies to require public disclosure of a study's underlying data and models as a prerequisite to the agency's consideration of the study when promulgating rules or developing influential information. Rather, the memo states only that "[a]gencies *should explore* methods that provide wider access to datasets while reducing the risk of disclosure of personally identifiable information."[147]

Second, in discussing reproducibility requirements for non-government information used by an agency, the 2019 OMB Memo states in implementation update 3.3 that:

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[142] *Id.*; *see also* EDF 2018 Comments at 34-35 (explaining how the 2018 proposal violates the 2002 OMB Regulations).

[143] 67 Fed. Reg. at 8460.

[144] *Panhandle Producers & Royalty Owners Ass'n v. Econ. Regulatory Admin.*, 822 F.2d 1105, 1110, (D.C. Cir. 1987) ("[W]hen an agency announces a policy shift in a nonbinding policy statement, the new policy is not 'binding precedent,' but 'is subject to complete attack before it is finally applied in future cases.'" (quoting *Pac. Gas & Elec. Co. v. FPC*, 506 F.2d 33, 39 (D.C. Cir. 1974)).

[145] *See* Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 66 Fed. Reg. 34,489 (June 28, 2001); 67 Fed. Reg. 8451; *see also* 5 U.S.C. § 553(b)-(d).

[146] 2019 OMB Memo at 8.

[147] *Id.* at 9 (emphasis added).

> Agencies should ensure that when using non-government sources to create influential information they communicate to the public sufficient information on the characteristics of the data and analysis, including its scope (e.g., temporal or demographic), generation protocols, and any other information necessary to allow the public *to reproduce the agencies' conclusions*.[148]

However, the 2019 OMB Memo is clear that to reproduce an agency's conclusions, the public need not access an entire underlying dataset or recreate the entire original study. Rather, "[t]he standard requires that influential analyses must be disseminated *with sufficient descriptions* of data and methods to allow them to be reproduced by qualified third parties who may want to test the sensitivity of agency analyses."[149] In other words, the 2019 OMB Memo states no requirement to publicly share the actual data underlying studies. Moreover, the language of the memo in no way authorizes EPA to prohibit consideration of, or discount, studies with underlying data that cannot be shared publicly. The proposed rule's automatic exclusion or discounting of studies for which underlying data and models are unavailable cannot be justified by this memo's language.

EPA's proposed regulations also directly conflict with the 2019 OMB Memo's clear instruction that "OMB policy requires agencies to ensure that privacy and confidentiality are fully protected."[150] Specifically, the memo confirms that "*[a]ll data disclosures must be consistent with statutory, regulatory, and policy requirements for protections of privacy and confidentiality, proprietary data, and confidential business information*."[151] Thus, even if the 2019 OMB Memo could override the OMB's 2002 Guidelines—which it cannot—there is no indication that OMB desired to alter the 2002 Guidelines' express declaration that data shall only be subjected to a reproducibility requirement if practicable "given ethical, feasibility, or confidentiality constraints" and that an agency "*shall not* require that all disseminated data be subjected to a reproducibility requirement."[152] In sum, the 2018 proposal and Supplemental Notice conflict with the plain meaning and intent of both the 2019 OMB Memo and the 2002 Guidelines. Thus, contrary to EPA's declared intention, the revised draft regulations presented in the Supplemental Notice continue to violate the Information Quality Act.[153]

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[148] *Id.* at 8.

[149] *Id*. at 7 (emphasis added).

[150] *Id.* at 5.

[151] *Id.* at 8 (emphasis added).

[152] 67 Fed. Reg. at 8,460 (emphasis added).

[153] Finally, although the IQA itself does not create a cause of action, *see Mississippi Comm'n on Envtl. Quality v. EPA*, 790 F. 3d 138, 184-85 (D.C. Cir. 2015), the IQA and OMB's implementing rules do create "meaningful standards" which are "judicially manageable" such that violation of these provisions can be held arbitrary and capricious under the Administrative Procedure Act. *See Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *16; *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 17-20 (1st Cir. 2020) (although FACA itself does not create

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III. THE SUPPLEMENTAL NOTICE CONTINUES TO VIOLATE NUMEROUS SUBSTANTIVE STATUTORY REQUIREMENTS

A. THE REVISED PROPOSED REGULATIONS CONTRAVENE REQUIREMENTS IN GOVERNING ENVIRONMENTAL AND PUBLIC HEALTH STATUTES REGARDING EPA'S OBLIGATION TO CONSIDER AVAILABLE SCIENTIFIC INFORMATION.

EPA's statutory authorities generally require the agency to consider all available science when undertaking significant rulemakings.[154] As the D.C. Circuit recently explained in *Physicians for Social Responsibility v. Wheeler*:

> Several environmental statutes require EPA to ground its decision-making in scientific evidence. The Clean Air Act, for example, mandates that "[a]ir quality criteria . . . accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare," 42 U.S.C. § 7408(a)(2), and the Toxic Substances Control Act requires the Administrator to "make decisions . . . based on the weight of the scientific evidence," 15 U.S.C. § 2625(i).[155]

The originally proposed regulatory language (§§ 30.3, 30.5) violated these statutory commands by preventing EPA from relying on a study as "pivotal regulatory science . . . used to justify significant regulatory decisions" if dose-response data or models underlying the study were not publicly available, without regard to whether the study had been validated by other means.[156] The Supplemental Notice exacerbates these violations by expanding the proposed regulation's scope (§§ 30.3, 30.5) to not just pivotal *regulatory* science used to justify significant *regulatory* decisions, but also "pivotal science supporting influential scientific information."[157]

Like the original proposal, the Supplemental Notice lacks any demonstration that the public unavailability of a study's underlying data or models necessarily—or even likely—renders the study invalid or unreliable. To the contrary, EDF and others argued extensively in comments on the original proposal that mechanisms are already in place to validate studies for which disclosure

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a cause of action, it supplies meaningful law to apply such that violation of its terms can be found arbitrary under the APA).

[154] EDF 2018 Comments at 14-32.

[155] *Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *3-4; *see also id.* at *26 ("EPA operates pursuant to multiple statutory mandates requiring that its decisions rest on various formulations of 'the best available science.' 15 U.S.C. § 2625(h).").

[156] 83 Fed. Reg. at 18,773 (emphases omitted).

[157] 85 Fed. Reg. at 15,405.

of underlying data and models is either illegal or impracticable.[158] Thus, EPA's automatic exclusion from consideration of (or, at least, diminished reliance upon) studies based solely on the public unavailability of underlying data or models would result in the agency failing to consider all available science—and even the best available science in some cases—in direct contravention of statutory requirements.

Just as EPA is required to consider all available science when making its regulatory decisions, governing environmental and public health statutes likewise require EPA to consider all available science when releasing "influential scientific information" (ISI), which often forms the basis for the agency's regulatory decisions. For example:

- Clean Air Act (CAA) section 108 instructs EPA to establish air quality criteria that "accurately reflect the latest scientific knowledge,"[159] which criteria, in turn, must inform national ambient air quality standards (NAAQS).[160] EPA's website identifies as "influential scientific information"[161] numerous products pertaining to the establishment of air quality criteria and revision of the NAAQS, such as the Office of Air and Radiation's "Ozone NAAQS Review: Risk/Exposure Assessment,"[162] and the Office of Research and Development's integrated science assessments for carbon monoxide,[163] lead,[164] oxides of nitrogen,[165] and sulfur oxides.[166]

- The Toxic Substances Control Act (TSCA) directs that, in implementing the Act's testing requirements, manufacturing and processing notice requirements, and requirements for the prioritization, risk evaluation, and regulation of chemical substances and mixtures, EPA must make its decisions "based on the weight of the scientific evidence."[167] Likewise, in carrying out EPA's responsibilities under TSCA, "the Administrator shall use scientific information . . . employed in a

[158] EDF 2018 Comments at 64-66, 70-74.

[159] 42 U.S.C. § 7408(a)(2).

[160] *Id.* § 7409(b).

[161] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm.

[162] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=OAQPS&dirEntryID=240406.

[163] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=213229.

[164] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=242655.

[165] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=189147.

[166] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=190346.

[167] 15 U.S.C. § 2625(i).

manner consistent with the best available science."[168] Numerous other TSCA provisions emphasize EPA's obligation to consider all reasonably available scientific information when implementing TSCA's requirements.[169] EPA's Science Inventory website identifies many products pertaining to its evaluation of the impact of toxic substances on human health and the environment, including products such as the Office of Chemical Safety and Pollution Prevention's "Exposure and Hazard Information for Five PBT Chemicals."[170]

- The Clean Water Act (CWA) instructs that EPA's water quality criteria must "accurately reflect[] the latest scientific knowledge" on a variety of factors.[171] Examples of CWA-related ISI identified on EPA's website include the Office of Research and Development's "Coral Reef Biological Criteria: Using the Clean Water Act to Protect a National Treasure," and "The Effects of Mountaintop Mines and Valley Fills on Aquatic Ecosystems of the Central Appalachian Coalfields."[172]

- The Safe Drinking Water Act (SDWA) generally requires EPA to use "the best available, peer-reviewed science,"[173] and to use the "best available public health information" when deciding whether to regulate a particular contaminant.[174] These standards certainly extend to EPA's SDWA-related ISI, such as the Office of Research and Development's "Assessment of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources" posted on EPA's Science Inventory website.[175]

- The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) states, among other things, that EPA and the Agency for Toxic Substances and Disease Registry (ATSDR) must annually update a list of hazardous substances commonly found at facilities on the National Priorities List that the agencies determine "pos[e] the most significant potential threat to human health due to their known or suspected toxicity to humans and the potential for human

[168] *Id.* § 2625(h).

[169] *See* EDF 2018 Comments at 25-31.

[170] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=OPPT&dirEntryID=342954.

[171] 33 U.S.C. § 1314(a)(1).

[172] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=215267.

[173] 42 U.S.C. § 300g-1(b)(3)(A)(i).

[174] *Id.* § 300g-1(b)(1)(B)(ii)(II).

[175] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=244651.

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> exposure to such substances . . .”[176] For each listed substance, ATSDR must develop a toxicological profile based on guidelines prepared by the EPA and ATSDR.[177] The profile must include examination of “available toxicological information and epidemiologic evaluations . . . to ascertain the levels of significant human exposure for the substance and the associated acute, subacute, and chronic health effects.”[178] Many products relating to CERCLA implementation, especially regarding the establishment of appropriate cleanup standards, are classified as ISI, such as the Office of Solid Waste and Emergency Response’s “Alternative Approach to Estimating Cancer Potency for Asbestos.”[179]

A rule that prohibits EPA from considering (or that downgrades) valid, high quality scientific studies when generating ISI such as the products identified above would contravene the above-noted statutory directives regarding EPA’s obligation to consider all available science.

While the ISI examples provided above involve scientific studies (or surveys of available information) designed to enable effective implementation of specific statutes, there are also many circumstances under which EPA develops ISI with broad applicability to multiple programs or varying governmental actions that have yet to be identified. Such products include Integrated Risk Information System (IRIS) chemical reviews by EPA’s Office of Research and Development (ORD) (*e.g.*, the 2019 “IRIS Toxicological Review of Ethyl Tertiary Butyl Ether (ETBE)”[180] and “IRIS Toxicological Review of Tert-Butyl Alcohol (TBA)”[181]), and reports by EPA’s Office of Chemical Safety and Pollution Prevention (*e.g.,* “Continuing Development of Alternative High-Throughput Screens to Determine Endocrine Disruption, Focusing on Androgen Receptor, Steroidogenesis, and Thyroid Pathways”[182]). EPA’s application of the proposed public disclosure regulations to such products is especially pernicious because it would likely be impossible—or at least, immensely burdensome—to determine at the time that the ISI is utilized in agency decision-making whether, in developing the ISI, EPA omitted from consideration (or gave lesser weight to) valid scientific studies that EPA is obligated to consider fully under the relevant statutory or regulatory provisions.

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[176] 42 U.S.C. § 9604(i)(2)(A), (B).

[177] *Id.* § 9604(i)(3).

[178] *Id.* § 9604(i)(3)(A).

[179] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=OPM&dirEntryID=134104.

[180] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=326410.

[181] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=322481.

[182] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=OSCP&dirEntryID=338571https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=226723.

For example, the purpose of ORD's IRIS chemical reviews is to support EPA's mission of protecting public health and the environment by identifying and characterizing the health hazards of chemicals found in the environment.[183] According to EPA's website, these reports "[a]re the preferred source of toxicity information used by EPA," and "[a]re an important source of toxicity information used by state and local health agencies, other federal agencies, and international health organizations."[184] The availability of these reports enables government regulators to act effectively and efficiently in promulgating rules and taking other actions needed to protect public health and the environment from toxic chemicals.[185] In particular, EPA's program and regional offices identify human exposure pathways and estimate the amount of human exposure under different exposure scenarios. They are then able to combine their exposure assessment with the hazard information and toxicity values from IRIS chemical reviews to characterize potential public health risks.[186] Among other things, EPA uses this information to help set national standards under TSCA,[187] the CAA,[188] the SDWA,[189] and the Emergency Planning and Community Right-to-Know Act,[190] and to clean up hazardous sites under CERCLA.[191] But none of these statutes allow EPA to ignore valid, pivotal scientific studies based solely on the fact that underlying data or models are not publicly available. If ORD is forced to exclude consideration of such studies when developing its IRIS chemical reviews, EPA's reliance on these reviews when taking actions under these statutes would be unlawful and arbitrary unless EPA combs through the report and available science to confirm that all valid studies have been considered.[192] The need to undertake such a comprehensive review of ISI before relying upon it would fundamentally undermine the purpose of preparing ISI for general use by EPA's various programs, offices, and regions. Thus, beyond the numerous statutory violations described above, EPA's failure to consider how its proposed rule could interfere with its ability to discharge its statutory duties and fulfill its mission of protecting

[183] EPA, Basic Information about the Integrated Risk Information System, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system.

[184] *Id.*

[185] *Id.*

[186] *Id.*

[187] *See, e.g.*, 82 Fed. Reg. 7432, 7446 (Jan. 19, 2017).

[188] *See, e.g.*, 79 Fed. Reg. 60,238, 60,246 (Oct. 6, 2014).

[189] *See, e.g.*, 79 Fed. Reg. 62,716, 62,735-36 (Oct. 20, 2014).

[190] *See, e.g.*, 59 Fed. Reg. 61,432, 61,444-45 (Nov. 30, 1994).

[191] *See, e.g.*, 53 Fed. Reg. 51,962 (Dec. 23, 1988) (§ 2.2.1.1).

[192] This outcome is especially likely if EPA succeeds in promulgating the proposed rule solely under the Housekeeping Statute and deferring any analysis of whether the rule violates the requirements of federal environmental and public health statutes until EPA takes an action specifically under one of these statutes. Unfortunately, by the time EPA is taking action that relies upon ISI like an IRIS report, it would be extremely difficult to remedy the violation, since the entire report would need to be reviewed and likely redone.

public health and the environment renders its proposed action arbitrary and capricious under the APA.[193]

B. The Supplemental Notice Would Violate the APA and EPA's Authorizing Statutes by Depriving the Public of an Adequate Opportunity to Comment on Future Rulemakings.

The Supplemental Notice would prevent the public from commenting meaningfully on future rulemakings by withholding information on the studies the agency is considering or will consider. In order to comment in an informed way, it is essential for the public to understand the agency's rationale for ignoring otherwise relevant information. If the agency fails to explain why it has excluded a study in issuing a proposal, or will not consider it when submitted by commenters, the public cannot object to its exclusion and has no indication whether the agency has rejected it because of the requirements of this rule or because the agency deemed the study irrelevant to its regulation. The latter, if true, would be crucial to an understanding of the agency's view of the scope and purpose of its regulation. Yet the Supplemental Notice suggests that EPA will only provide an explanation for disregarding or discounting a study under its alternative "weighting" option.[194] It has not indicated that it will identify the studies it has entirely ruled out under the preferred "tiered access" approach.[195] Without an understanding of how this rule is operating to suppress scientific information in future rulemakings, commenters cannot understand the basis of the agency's proposals and may develop and submit information that the agency will discard out of hand. They would also be unable to oppose EPA's disregard of otherwise relevant information, which it may be required to consider under the controlling statute. This 'black box' precludes fully informed comment on future rulemakings and therefore violates the APA and EPA's authorizing statutes.[196]

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[193] *See Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *27 ("[I]n failing to grapple with how EPA's policy affected its statutory scientific mandates, the Directive 'failed to consider an important aspect of the problem.' *State Farm*, 463 U.S. at 42.").

[194] 85 Fed. Reg. at 15,402.

[195] *See id.* at 15,402-03.

[196] *See, e.g., Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 239-40 (D.C. Cir. 2008) ("It is [acceptable] for the Commission to give notice and make available for comment the studies on which it relied in formulating the rule while explaining its non-reliance on certain parts." (emphasis added)); *cf. Appalachian Power Co. v. EPA*, 249 F.3d 1032, 1060 (D.C. Cir. 2001) (upholding EPA's fully explained determination that a report did not need to be included in the docket because it was not of central relevance to the rulemaking).

C. EPA Cannot Issue a Rule That Violates Other Statutes by Noting that the Other Statutes Are Controlling Only When They Apply.

Facing the plethora of statutory violations documented above, EPA must withdraw the Supplemental Notice as inconsistent with its substantive obligations to use the best available science. Apparently anticipating these conflicts, EPA concedes that:

> This internal agency procedure is intended to be consistent with the statutes that EPA administers and EPA plans to implement this procedural rulemaking in accordance with all applicable statutory and regulatory requirements. . . . Nonetheless, in the event the procedures outlined in the proposed rulemaking conflict with the statutes that EPA administers, or their implementing regulations, the statutes and regulations will control.[197]

This rationale is vague and meaningless. As an initial matter, EPA has not explained how its rule is "intended to be consistent with" the statutes it administers, nor has it attempted to identify the areas of conflict it anticipates, which renders its promise to yield to their requirements arbitrary.[198] Even if it had offered some indication of the conflicts it foresees, its protean response is ineffectual: to the extent that the agency seeks to inoculate its rule against legal challenges based on these statutory violations, any invalid application—of the many that would proliferate upon implementation—would doom the rule.[199] EPA cannot insulate its unlawful policy from challenges by promising to yield in the future to statutory and regulatory requirements.[200]

Nor does EPA enhance its rule with the mere suggestion that its options for considering studies in some circumstances "improve consistency" with statutes requiring use of the best available science.[201] Aside from the inherent flaws in these approaches, discussed in greater detail

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[197] 85 Fed. Reg. at 15,398; *see also id.* at 15,405 (proposed 40 C.F.R. § 30.3).

[198] *See Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *27 ("[I]n failing to grapple with how EPA's policy affected its statutory scientific mandates, the Directive 'failed to consider an important aspect of the problem.' State Farm, 463 U.S. at 42."). EPA's expectation that its proposed rule would contravene the statutes it administers also calls into question any reliance on them as authority for this action.

[199] *See Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998); *District of Columbia v. U.S. Dep't of Agric.*, No. 20-119 (BAH), 2020 U.S. Dist. LEXIS 43853, at *100-04 (D.D.C. Mar. 13, 2020).

[200] *See Ameren Servs. Co. v. FERC*, 880 F.3d 571, 584 (D.C. Cir. 2018) ("We once described an agency's effort to offer future rulemaking as a response to a claim of agency illegality as an 'administrative law shell game,' *Am. Tel. & Tel. Co. v. FCC*, 978 F.2d 727, 732, 298 U.S. App. D.C. 230 (D.C. Cir. 1992), a phrase the Supreme Court thought apt. *See MCI Telecomm. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 222, 114 S. Ct. 2223, 129 L. Ed. 2d 182 (1994).").

[201] 85 Fed. Reg. at 15,398.

below, occasional compliance with statutory requirements cannot render its rule lawful.[202] To correct the numerous statutory violations documented above,[203] EPA must conform its actions to the directives Congress imposed; partial alignment will not suffice.

IV. THE SUPPLEMENTAL NOTICE'S EXPANDED SCOPE COMPOUNDS ITS ARBITRARINESS AND UNLAWFULNESS

A. EPA Dramatically Extends the Reach of Its Proposal Without Adequate Explanation.

1. *EPA Fails to Provide a Sufficient Description and Explanation of Its Proposal to Exclude Studies for Which Any of the Underlying Data and Models Are Not Publicly Available.*

The original proposal applied to "dose response data and models that underlie . . . pivotal regulatory science."[204] The Supplemental Notice expands its application to all "data and models" underlying "pivotal regulatory science and pivotal science,"[205] but leaves considerable and unacceptable uncertainty as to the breadth of this expansion. EPA offers only a sampling of the types of scientific information that it might disregard:

> Some, but not the only, examples of information that would be considered to be data and models, in addition to dose-response data and dose-response models, include environmental fate studies, bioaccumulation data, water-solubility studies, environmental fate models, engineering models, data on environmental releases,

[202] *See U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 643 (D.C. Cir. 2016).

[203] *See* Section III.A, *supra*.

[204] 83 Fed. Reg. at 18,770. "Pivotal regulatory science" is described in the preamble of the original proposal as "the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based." *Id.* The proposed regulatory definition of "pivotal regulatory science" in the original proposal is "the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions." *Id.* at 18,773.

[205] 85 Fed. Reg. 15,396. The proposed regulatory definition of "pivotal science" in the Supplemental Notice is "the specific scientific studies or analyses that underly [sic] influential scientific information" and the proposed regulatory definition for "influential scientific information" in the Supplemental Notice is "scientific information that will have or does have a clear and substantial impact on important public policies or private sector decisions." *Id.* at 15,405.

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> exposure estimates, quantitative structure activity relationship data, and environmental studies.[206]

EPA admits that this list is incomplete—and it is plainly incoherent, ranging from data to models to studies to estimates. Further, upon review of the Supplemental Notice, the SAB has concluded that the definitions of "data and models" "are not adequate."[207] By failing comprehensively to describe the scope of its proposal, EPA has denied the public the information it needs to comment in an informed way.[208]

Nonetheless, EDF has investigated potential areas of application—an exercise that explores the serious consequences the rule could have, but which cannot fulfill the agency's obligation to provide adequate notice of the scope of its rule. Examples we've identified include:

Integrated Science Assessment for Particulate Matter

In April 2020, EPA proposed to retain the existing National Ambient Air Quality Standards (NAAQS) for particulate matter (PM), one of the six criteria air pollutants.[209] EPA's proposal is based in part on the agency's Integrated Science Assessment (ISA) for PM[210] that surveyed and synthesized the body of scientific evidence on the health and welfare effects of PM, including data and studies published since the previous review of the NAAQS in 2012.[211] The ISA is identified by EPA as highly influential scientific information, and as such would have been subject to the proposed rule's requirements if they had been in place.[212]

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[206] *Id.* at 15,400; *see also id.* at 15,401 ("This list is not exhaustive but is intended to provide examples of the range of information that would be considered to be within the scope of data and models.").

[207] Final SAB Report at 3; *see also id.* at 11 (stating that EPA "should define and clarify when the requirements are applicable to animal toxicity studies or environmental epidemiology studies"). The SAB suggests that EPA could elaborate on these definitions in a guidance document. *Id.* For the reasons discussed above, however, subsequently issued guidance would not provide the requisite notice and allow for informed public comment on the scope of EPA's proposed rule.

[208] *See Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983) ("Agency notice must describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decisionmaking."); *see also id*. ("This is doubly true under Clean Air Act § 307(d)(3), which requires EPA to issue a specific 'proposed rule' as a focus for comments.").

[209] Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094 (Apr. 30, 2020).

[210] Integrated Science Assessment for Particulate Matter, 85 Fed. Reg. 4655 (Jan. 27, 2020).

[211] National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3086 (Jan. 15, 2013).

[212] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm.

PM is associated with several adverse health effects, including eye and respiratory irritation, breathing issues, asthma, and lung cancer, and poses particular risks to certain susceptible subpopulations such as those with heart and lung diseases, children, and the elderly.[213] Despite the evidence that PM negatively affects human health and welfare, including new studies published since the previous review of the NAAQS, EPA's decision to retain the existing NAAQS for PM fails to adequately protect public health.[214] These comments do not address the merits of EPA's proposal to retain the existing NAAQS for PM nor the PM ISA, and instead focus solely on illustrating the significant effects the proposal would have on a recent EPA product.

The PM ISA reviews thousands of studies relevant to the pollutant, ranging from its sources and atmospheric chemistry to its associations with various adverse health outcomes. A broad assessment that synthesizes a large body of evidence, the ISA for PM would be significantly affected by EPA's proposal, especially given the proposal's expansion to *all* data and models not only dose-response data and models. For example, in the section on sources, atmospheric chemistry, and ambient concentrations, the data underlying two of the studies cited as evidence that vehicle emissions are the primary source of PM pollution in the United States are not publicly available.[215] Similarly, the underlying data are not publicly available for a large fraction of the studies that EPA relies on to characterize chemical transport and national-level ambient concentrations of PM. As just a few examples, Crippa et al. 2009, Paciorek & Liu 2009, and Matte et al. 2013 provide critical information on the accuracy of regional chemical transport models, the efficacy of using remote sensing data to estimate ground-level PM, and the patterns of air pollution across an urban landscape, respectively, yet the data underlying these studies are not publicly available.[216]

Exposure information is another critical component of ISAs. In the case of PM, there are numerous exposure studies for which the underlying data are not publicly available. Among these

[213] CDC, Particle Pollution, https://www.cdc.gov/air/particulate_matter.html.

[214] Press Release, American Lung Association, 19 Health and Medical Organizations Strongly Oppose EPA's Move to Keep Weak Limits on Particle Pollution, Placing Health of Millions at Risk (Apr. 14, 2020), https://www.lung.org/media/press-releases/health-organizations-epa-particle-pollution; Clean Air Task Force, Statement on EPA Proposal on NAAQS (Apr. 14, 2020), https://www.catf.us/2020/04/catf-statement-on-epa-proposal-on-naaqs/.

[215] A. Fushimi et al., *Chemical Composition and Source of Fine and Nanoparticles from Recent Direct Injection Gasoline Passenger Cars: Effects of Fuel and Ambient Temperature*, 124 ATMOSPHERIC ENV'T 77 (2016); L. Morawska et al., *Ambient Nano and Ultrafine Particles from Motor Vehicle Emissions: Characteristics, Ambient Processing and Implications on Human Exposure*, 42 ATMOSPHERIC ENV'T 35 (2008).

[216] P. Crippa et al., *Evaluating the Skill of High-Resolution WRF-Chem Simulations in Describing Drivers of Aerosol Direct Climate Forcing on the Regional Scale*, 16 ATMOSPHERIC CHEMISTRY AND PHYSICS 1 (2016); .D. Matte et al., *Monitoring Intraurban Spatial Patterns of Multiple Combustion Air Pollutants in New York City: Design and Implementation*, 23 J. EXPOSURE SCI. AND ENVTL. EPIDEMIOLOGY 3 (2013); C.J. Paciorek & Y. Liu, *Limitations of Remotely-Sensed Aerosol as a Spatial Proxy for Fine Particulate Matter*, 117 ENVTL. HEALTH PERSPECTIVES 6 (2009).

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are studies that explore differences in personal exposure based on an individual's surrounding environment,[217] as well as those that explore exposure levels among certain vulnerable populations[218] and that characterize the relationship between long-term exposure to PM and adverse health outcomes.[219]

All of the studies cited here have been vetted through established, peer-reviewed processes and EPA has relied upon them to develop the PM ISA. The two alternative approaches outlined in EPA's proposal would not resolve the limitations imposed on the agency's use of these studies by the proposal. Under the tiered access approach, those studies that do not utilize restricted data or models would be immediately excluded; while studies that contain restricted data or models would be excluded unless the authors are somehow able to miraculously comply with the agency's entirely ambiguous tiered access regime. As discussed in Section I.D, *supra*, and Section V.B, *infra*, researchers would be unable or unlikely to surmount the massive obstacles involved in providing tiered access to restricted data assuming they would even attempt it. Under the differential weighting approach, the studies cited here would either be excluded outright or be given less consideration, either outcome of which would result in the agency's failure to use the best available science, ultimately violating the Clean Air Act when revising the NAAQS.[220]

Integrated Science Assessment for Sulfur Oxides

In 2019, EPA issued a decision to retain the previous primary NAAQS for sulfur oxides (SOx), another of the six criteria air pollutants.[221] As with particulate matter, the NAAQS decision for SOx was based in part on an ISA that reviewed and synthesized the body of scientific evidence on the health and welfare effects of this pollutant.[222] EPA identified the SOx ISA as highly

[217] R.W. Allen et al., *Modeling the Residential Infiltration of Outdoor PM(2.5) in the Multi-Ethnic Study of Atherosclerosis and Air Pollution (MESA Air)*, 120 ENVTL. HEALTH PERSPECTIVES 6 (2012); M.L. Bell et al., *Adverse Health Effects of Particulate Air Pollution: Modification by Air Conditioning*, 20 EPIDEMIOLOGY 5 (2009); Q. Meng et al., *Determinants of the Associations Between Ambient Concentrations and Personal Exposures to Ambient PM2.5, NO2, and O3 During DEARS*, 63 ATMOSPHERIC ENV'T 109 (2012).

[218] L. Liu et al., *Acute Effects of Air Pollution on Pulmonary Function, Airway Inflammation, and Oxidative Stress in Asthmatic Children*, 117 ENVTL. HEALTH PERSPECTIVES 4 (2009).

[219] M. Jerrett et al., *Comparing the Health Effects of Ambient Particulate Matter Estimated Using Ground-Based Versus Remote Sensing Exposure Estimates*, 125 ENVTL. HEALTH PERSPECTIVES 4 (2016); J. Madrigano et al., *Long-Term Exposure to PM2.5 and Incidence of Acute Myocardial Infarction*, 121 ENVTL. HEALTH PERSPECTIVES 2 (2013).

[220] 42 U.S.C. §§ 7408(a)(2), 7409(d)(1).

[221] Review of the Primary National Ambient Air Quality Standards for Sulfur Oxides, 84 Fed. Reg. 9866 (Mar. 18, 2019).

[222] Integrated Science Assessment for Sulfur Oxide—Health Criteria, 82 Fed. Reg. 58,600 (Dec. 13, 2017).

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influential scientific information,[223] and as such the ISA would have been subject to the proposed rule's requirements if they had been in place.

Sulfur oxides are associated with harmful health effects, including irritation of the respiratory tract and asthma exacerbation, while high levels of exposure are associated with difficulty breathing, adverse effects on lung function, and exacerbations of existing heart disease.[224] Especially vulnerable groups include those with lung diseases, children, and the elderly.

The SOx ISA reviews thousands of studies, models, and technical reports relevant to the pollutant. As with the PM ISA, the ISA for SOx would be significantly affected by EPA's proposal, as a number of studies that the assessment relies upon do not have publicly available underlying data. Again, this includes non-dose response studies now captured by the Supplemental Notice. For example, the underlying data are not publicly available for Horowitz et al. 2003, a study that developed a chemical transport model used to inform conclusions about the effects of atmospheric chemistry on large-scale changes in ambient concentrations of various air pollutants.[225] Among the subset of SOx exposure studies that EDF reviewed, a large fraction did not have publicly available underlying data, including studies the ISA cites when describing individual exposure to sulfur dioxide, the connection between SOx pollution and mortality, and the relationship between ambient environmental conditions and individual exposure levels to SOx.[226] Key studies examining the health effects of SOx and identifying vulnerable subpopulations would also be affected by EPA's proposal as their underlying data are not publicly available. Just a few examples of such studies include those demonstrating the unique susceptibilities of asthmatic individuals, including asthmatic children, to sulfur dioxide, as well as investigations that reveal decreased lung function among otherwise healthy individuals living near an industrial facility that releases sulfur dioxide.[227]

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[223] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm.

[224] National Park Service, Sulfur Dioxide Effects on Health, https://www.nps.gov/subjects/air/humanhealth-sulfur.htm.

[225] L.W. Horowitz et al., *A Global Simulation of Tropospheric Ozone and Related Tracers: Description and Evaluation of MOZART, Version 2*, 108 J. GEOPHYSICAL RESEARCH D24 (2003).

[226] R. Beelen et al., *Estimated Long-Term Outdoor Air Pollution Concentrations in a Cohort Study*, 41 ATMOSPHERIC ENV'T 7 (2007); K.W. Brown et al., *Factors Influencing Relationships Between Personal and Ambient Concentrations of Gaseous and Particulate Pollutants*, 407 SCI. TOTAL ENV'T 12 (2009); B. Zou et al., *An Emission-Weighted Proximity Model for Air Pollution Exposure Assessment*, 407 SCI. TOTAL ENV'T 17 (2009).

[227] R. Dales et al., *Acute Changes in Lung Function Associated with Proximity to a Steel Plant: A Randomized Study*, 55 ENV'T INTL. 15 (2013); W.S. Linn et al., *Responses to Sulfur Dioxide and Exercise by Medication-Dependent Asthmatics: Effect of Varying Medication Levels*, 45 ARCH. ENVTL. & OCCUPATIONAL HEALTH 1 (1990); H. Velická et al., *Asthma Exacerbations and Symptom Variability in Children Due to Short-Term Ambient Air Pollution Changes in Ostrava, Czech Republic*, 23 CENT. EUR. J. PUB. HEALTH 4 (2015).

All of the studies cited here have been vetted through established, peer-reviewed processes and EPA has relied upon them to develop the SOx ISA. As described above for the PM ISA, the alternative approaches outlined in the proposal, tiered access and differential weighting, would not resolve the limitations imposed on the agency's use of these studies. Both approaches would limit the body of evidence that EPA can use to reach conclusions in the ISA and would therefore prevent the agency from setting NAAQS for sulfur oxides based on the best available science, again violating the Clean Air Act when revising the NAAQS.[228]

Assessment of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on U.S. Drinking Water Resources

In 2016, EPA published a report examining the potential impacts of hydraulic fracturing activities on drinking water in the U.S., *Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States*.[229] EPA identified the external review draft and the final report as highly influential scientific information, and as such both would have been subject to the proposed rule's requirements had they been in place.

The report reviews and synthesizes the body of scientific evidence relevant to five major activities in the hydraulic fracturing water cycle—water acquisition, chemical mixing, well injection, flowback and produced water, and wastewater treatment and waste disposal—and characterizes their potential to affect the quality and quantity of drinking water resources. As stated in the report, its purpose is to provide government and other stakeholders with a comprehensive report of the best available science that may be used to support decisions related to hydraulic fracturing and drinking water resources.

The report reviews thousands of studies and other data sources relating to key activities of the hydraulic fracturing water cycle. EDF reviewed a subset of the studies cited in the report and found that a number of them do not make their underlying data publicly available. For example, two of the studies that the report cites when describing the potential for surface water contamination due to oil and gas development, as well as the scale of this potential in locations with intensive development, do not have publicly available underlying data.[230] The same is true

[228] 42 U.S.C. §§ 7408(a)(2), 7409(d)(1).

[229] EPA, *Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States* (2016) ("Hydraulic Fracturing Report"), https://cfpub.epa.gov/ncea/hfstudy/recordisplay.cfm?deid=332990.

[230] S. Entrekin et al., *Rapid Expansion of Natural Gas Development Poses a Threat to Surface Waters*, 9 FRONTIERS IN ECOLOGY ENV'T 9 (2011); A. Vengosh et al., *A Critical Review of the Risks to Water Resources from Unconventional Shale Gas Development and Hydraulic Fracturing in the United States*, 48 ENVTL. SCI. & TOXICOLOGY 5 (2014).

for studies that describe the transport of volatile organic compounds (VOCs) and other byproducts of oil and gas extraction through soil and groundwater.[231] Similarly, two studies that found an association between shale gas development and water quality degradation at local and regional scales, and that the report cites when discussing wastewater treatment and waste disposal, do not have publicly available underlying data.[232]

All of the studies described here have been vetted through established, peer-reviewed processes and EPA has relied upon them to develop this report of the potential impacts of hydraulic fracturing on drinking water resources. In describing this publication EPA indicated that, "the scientific information presented can be used by federal, tribal, state, and local officials; industry; and the public to better understand and address vulnerabilities of drinking water resources to activities in the hydraulic fracturing water cycle."[233] EPA's proposal would undermine comprehensive, foundational scientific reports like this one, undercutting efforts of diverse stakeholders to make robust, health- and environmentally-protective decisions based on the best available science.

Future Influential Scientific Information and Significant Regulatory Decisions Regarding Novel Coronavirus, SARS-CoV-2

The ongoing global pandemic of COVID-19, the disease caused by novel coronavirus SARS-CoV-2, that began in late 2019 has had well-documented, disastrous effects on public health and economic well-being in the US and around the world. While researchers, public health agencies, and healthcare workers have been racing to study the virus and develop treatments, many aspects of this crisis are still not well understood, including what personal and environmental risk factors, such as smoking or living in a region with high levels of air pollution, may make an individual more susceptible to contracting and succumbing to the disease.[234]

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[231] D. Bouchard et al., *Analytical Modelling of Stable Isotope Fractionation of Volatile Organic Compounds in the Unsaturated Zone*, 119 J. CONTAMINANT HYDROLOGY 1-4 (2011); E. Rasa et al., *Impacts of an Ethanol-Blended Fuel Release on Groundwater and Fate of Produced Methane: Simulation of Field Observations*, 48 WATER RESOURCES RES. 8 (2013); M.O. Rivett et al., *Review of Unsaturated-Zone Transport and Attenuation of Volatile Organic Compound (VOC) Plumes Leached from Shallow Source Zones*, 123 J. CONTAMINANT HYDROLOGY 3-4 (2011).

[232] S.M. Olmstead et al., *Shale Gas Development Impacts on Surface Water Quality in Pennsylvania*, 110 PROC. NAT'L ACAD. SCI. 13 (2013); R.D. Vidic et al., *Impact of Shale Gas Development on Regional Water Quality*, 340 SCIENCE 6134 (2013).

[233] Hydraulic Fracturing Report, *supra* note 229, at 10-28.

[234] For discussion of how some of these factors may make an individual more susceptible to COVID-19, *see* Environmental Defense Fund, *The Truth About Coronavirus, Air Pollution and Our Health* (Apr. 7, 2020), https://www.edf.org/blog/2020/04/07/truth-about-coronavirus-air-pollution-and-our-health.

It has become clear that this pandemic will be an ongoing global challenge at least until an effective vaccine is developed and widely distributed. EPA has a number of COVID-related efforts underway,[235] and is likely to produce influential scientific information, if not make significant regulatory decisions, regarding COVID-19. Yet EPA's proposal would hinder the agency's ability to do so using the best available scientific evidence, as many studies in the rapidly growing body of literature on COVID-19 do not provide publicly available underlying data. For example, three early cohort studies examining potential risk factors and outcomes among patients with COVID-19 provide only summary data.[236] Similarly, underlying data are not publicly available for two clinical studies reporting on disease progression and outcomes among COVID-19 patients.[237] Such studies provide valuable data about COVID-19 and the factors that may make certain individuals more susceptible to the disease, critical information to consider when examining the influence of environmental factors on the disease. Yet, EPA would be precluded from using these studies when developing influential scientific information or significant regulatory decisions under its proposal. The fact that EPA's proposal might require the agency to disregard critical studies aimed at better understanding an unprecedented global health threat further highlights the capriciousness and profoundly irresponsible nature of the proposal.

These case studies may be just the tip of the iceberg. Indeed, the scope of the Supplemental Notice's expansion appears well-nigh incalculable. We also looked at one section of a single rulemaking: EPA and NHTSA's October 25, 2016, final rule adopting greenhouse gas emission standards and fuel efficiency standards for medium- and heavy duty engines and vehicles.[238] Specifically, we examined the discussion of the heavy duty rule's potential impacts on a) emissions of greenhouse gases and resulting impacts on the climate;[239] b) criteria pollutant emissions and health effects of those pollutants;[240] c) emissions of air toxics and health effects of those

[235] *See* EPA, Coronavirus (COVID-19), https://www.epa.gov/coronavirus.

[236] W. Liu et al., *Analysis of Factors Associated with Disease Outcomes in Hospitalized Patients with 2019 Novel Coronavirus Disease*, 133 CHINESE MED. J. (ENGLISH) 9 (2020); H. Qiu et al., *Clinical and Epidemiological Features of 36 Children with Coronavirus Disease 2019 (COVID-19) in Zhejiang, China: An Observational Cohort Study*, LANCET INFECTIOUS DISEASES (2020), https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30198-5/fulltext; F. Zhou et al., *Clinical Course and Risk Factors for Mortality of Adult Inpatients with COVID-19 in Wuhan, China: A Retrospective Cohort Study*, 395 LANCET 10229 (2020).

[237] H. Shi et al., *Radiological Findings from 81 Patients with COVID-19 Pneumonia in Wuhan, China: A Descriptive Study*, 20 LANCET INFECTIOUS DISEASES 4 (2020); J. Zhang et al., *Clinical Characteristics of 140 Patients Infected with SARS-CoV-2 in Wuhan, China*, ALLERGY (2020), https://onlinelibrary.wiley.com/doi/full/10.1111/all.14238.

[238] Greenhouse Gas Emissions and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles—Phase 2, 81 Fed. Reg. 73,478 (Oct. 25, 2016).

[239] 81 Fed. Reg. at 73,833-35 nn.554-569; *id.* at 73,875-876 nn.833-35.

[240] 81 Fed. Reg. at 73,836-41 nn.570-609. Among these references are the NAAQS ISAs which are themselves compendia of research studies, each of which appears to be influential scientific information under the proposal.

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pollutants;[241] d) near road pollution;[242] and e) energy security benefits.[243] The total number of references in this single preamble section of a single rule is massive. Each reference appears to be "influential scientific information"—it has "a clear and substantial impact on important public polic[y] . . . decisions." That is why EPA cited and disseminated it as support for the positive environmental effects and energy security benefits resulting from its action. Each reference, in turn, is supported by bodies of sub-references which may also be influential scientific information. Or perhaps some, most, or even all these thousands of references and embedded sub-references are "pivotal science," since arguably they underlie disseminated influential scientific information,[244] or "pivotal regulatory science," since they apparently drive the requirements or quantitative analysis of EPA final significant regulatory decisions.[245] One cannot reliably answer given the opaque Supplemental Notice text—yet another instance of faulty notice.[246] What is clear is that thousands of items are affected and that EPA has made no analysis which accounts for those impacts.

EPA must, if it is to finalize any rule similar to the proposal, document whether or not these studies could be barred or limited in consideration under the proposed rule, the reasons why, and a rationale for why this is or is not reasonable. Which of the many studies cited in Heavy Duty Vehicle Rule would be barred or downgraded from consideration under the proposal?[247] Then, at a minimum, EPA should do this same analysis and provide a comparable explanation for the references in other of its significant rules. This of course is what EPA should have done already, and is required to do under standard administrative law principles requiring an agency to consider critical issues, and to identify and explain to the public the implications of its proposed actions.[248] Since none of this information is presently available to commenters, this notice is inadequate and

[241] 81 Fed. Reg. at 73,841-44 nn.610-679 (health effects of napthalene, acrolein, toluene, xylene, ethylbenzene, propionaldehyde, benzene, 1,3 butadiene, formaldehyde, polycyclic organic matter, among others; many of the references are IRIS databases, each of which contain many hundreds of supporting references which are also likely influential scientific information under the proposal).

[242] 81 Fed. Reg. at 73,844-46 nn.681-710.

[243] 81 Fed. Reg. at 73,888-92.

[244] *See* 83 Fed. Reg. at 18,773 (proposed 40 C.F.R. § 30.2).

[245] *See* 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

[246] *Cf. Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 158-59 (2012) ("[I]t is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance.").

[247] Is Karner, A.A. et al., *Near-Roadway Air Quality Data*, 44 ENV. SCI. TECH. 5334 (2010), barred or downgraded from consideration under the proposal (n.681)? Is "Health Effects Institute Panel on the Health Effects of Traffic Related Air Pollution (2010)" (n.689)? Is Zanobetti et al., *T-Wave Alternans, Air Pollution and Traffic in High-Risk Subjects*, 104 AM. J. CARDIOLOGY 665-670 (2009)?

[248] *State Farm*, 463 U.S. at 43; *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 518-19, 550.

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the public comment period is insufficient to fulfill EPA's public participation obligations. EPA must produce such analysis and then afford additional public notice and opportunity to comment on its findings.

The Supplemental Notice's extension to all models also has startling implications, to which EPA appears oblivious. The definition is stunningly broad: "Model means a simplification of reality that is constructed to gain insights into select attributes of a physical, biological, economic, or social system."[249] Given this nearly limitless reach, what are the proposal's implications for such fate and transport models as GREET[250] and MOVES[251]? What are the implications of exposure and monetization models such as BEN-Map CE?[252] Are econometric models including the proprietary Integrated Planning Model (IPM)[253] used in numerous significant rulemakings (including those recently carried out by this EPA) to evaluate impacts of air and water pollution standards[254] on electricity generating units implicated, why and how? Models for assessing effects

[249] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

[250] Greenhouse Gases, Regulated Emissions, and Energy Use in Transportation (GREET) is a full life-cycle model sponsored by the Argonne National Laboratory (U.S. Department of Energy's Office of Energy Efficiency and Renewable Energy). It fully evaluates energy and emission impacts of advanced and new transportation fuels, the fuel cycle from well to wheel, the vehicle cycle through material recovery, and vehicle disposal. It allows researchers and analysts to evaluate various vehicle and fuel combinations on a full fuel-cycle/vehicle-cycle basis. GREET includes more than 100 fuel production pathways and more than 70 vehicle/fuel systems.

[251] Motor Vehicle Emission Simulator (MOVES) is a state-of-the-science emission modeling system that estimates emissions for mobile sources at the national, county, and project level for criteria air pollutants, greenhouse gases, and air toxics.

[252] BenMAP-CE is an open-source computer program that calculates the number and economic value of air pollution-related deaths and illnesses. The software incorporates a database that includes many of the concentration-response relationships, population files, and health and economic data needed to quantify these impacts. BenMAP-CE enables users to load their own data or use pre-loaded datasets for the U.S. and China, including air quality data, demographic data, economic values, and concentration-response relationships.

[253] The Integrated Planning Model (IPM) is a multi-regional, dynamic, deterministic linear programming model of the U.S. electric power sector. It provides forecasts of least-cost capacity expansion, electricity dispatch, and emission control strategies for meeting energy demand and environmental, transmission, dispatch, and reliability constraints. IPM can be used to evaluate the cost and emissions impacts of proposed policies to limit emissions of sulfur dioxide (SO2), nitrogen oxides (NOx), carbon dioxide (CO2), hydrogen chloride (HCl), and mercury (Hg) from the electric power sector.

[254] *See* EPA, Regulatory Impact Analysis for the Repeal of the Clean Power Plan, and the Emission Guidelines for Greenhouse Gas Emissions from Existing Electric Utility Generating Units 3-4 (June 2019) ("The EPA has used IPM extensively over the past two decades to analyze options for reducing power sector emissions. Previously, the model has been used to forecast the costs, emission changes, and power sector impacts for the Clean Air Interstate Rule (CAIR), Cross-State Air Pollution Rule (CSAPR), the Mercury and Air Toxics Standards (MATS), and the Clean Power Plan (CPP). IPM has also been used to estimate the air pollution reductions and power sector impacts of water and waste regulations affecting EGUs, including Cooling Water Intakes (316(b)) Rule, Disposal of Coal Combustion Residuals from Electric Utilities (CCR) and Steam Electric Effluent Limitation Guidelines (ELG).").

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of climate change, including MAGICC[255] and GCAM[256]? Again, it is incumbent on EPA to evaluate the potential impacts of the Supplemental Notice on all of its standard modeling tools and its reasoning therefor, and then to provide notice and opportunity for comment on these findings.

EPA must also provide a well-reasoned justification for the expansion of its proposal, which it has not done. Previously, commenters objected to EPA's unjustified targeting of dose-response studies for exclusion, without any evidence that these studies are inherently less reliable than other studies.[257] Rather than fill this fundamental gap in the logic of the original proposal, the Supplemental Notice would extend the arbitrary and unsupported exclusion to *all* studies for which any underlying data or models are unavailable.[258] As with dose-response data and models, however, EPA has offered no reason why the additional data and models are also unreliable. Instead, it simply notes that other data and models, beyond dose-response data and models, will also influence its regulatory decisions and influential scientific information.[259] This fact is not an adequate explanation for excluding additional studies, and the Supplemental Notice remains as arbitrary as the original.

2. EPA Fails to Provide a Sufficient Description and Explanation of Its Proposal to Apply Its Rule to Influential Scientific Information.

At the same time, the Supplemental Notice expands the reach of the original proposal to all "pivotal science" underpinning influential scientific information, capturing a broad spectrum of scientific products developed by the agency. A review of an EPA webpage providing a chronological listing of published influential scientific information illustrates the breadth of agency activities now captured.[260] Taken from this webpage, examples of influential scientific information already published include all chemical toxicological reviews by the Integrated Risk

[255] Model for the Assessment of Greenhouse Gas Induced Climate Change, often used by the IPCC and cited repeatedly by EPA.

[256] Global Change Assessment Model (GCAM) is an integrated assessment model that links the world's energy, agriculture and land use systems with a climate model. The model is designed to assess various climate change policies and technology strategies for the globe over long time scales. GCAM runs in 5-year time steps from 1990 to 2100 and includes 14 geographic regions in the energy/economy module and 151 regions in the agriculture and land use module. The model tracks emissions and atmospheric concentrations of greenhouse gases (CO2 and non-CO2), carbonaceous aerosols, sulfur dioxide, and reactive gases and provides estimates of the associated climate impacts, such as global mean temperature rise and sea level rise.

[257] EDF 2018 Comments at 79-80.

[258] *Cf. State Farm*, 463 U.S. at 46-49 (faulting the agency for rescinding an entire safety standard without considering the effectiveness of airbags merely because the agency had determined that one option, automatic seatbelts, was ineffective).

[259] 85 Fed. Reg. at 15,399-400.

[260] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm.

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Information System (IRIS) program; all draft risk evaluations under the Toxic Substances Control Act; all integrated science assessments (ISAs); various EPA models and methods including those relating to hazard identification, exposure estimation, and environmental fate; and significant agency reports detailing the state of knowledge on issues of great import to protecting public health and the environment (e.g., impacts of climate change on human health in the United States, potential impacts of hydraulic fracturing on drinking water in the United States). A separate EPA webpage identifies planned and ongoing influential scientific information.[261] Examples of influential scientific information provided on this webpage include a biologically-based dose response model for perchlorate;[262] a model for estimating blood lead levels in children resulting from exposures via drinking water; and health effects documents for the per- and polyfluoroalkyl substances (PFAS) perfluorooctanoate (PFOA) and perfluorooctane sulfonate (PFOS). Notably, the agency did not identify these webpages to document the scope of its proposal, leaving open the possibility that it extends much further.

As with its incomplete list of examples of data and models, EPA has failed to provide adequate notice of the types of influential scientific information to which its rule could apply. Without such a comprehensive description, commenters are left with an exceedingly broad definition: "*Influential scientific information* means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions."[263] Although some influential scientific information could have been indirectly excluded from use by the agency by the original proposal—e.g., if destined to support a significant regulatory decision—the Supplemental Notice imposes an independent and immediate restriction on the development of *all* influential scientific information. EPA cannot reasonably expect commenters to anticipate the reach of its new proposal or account for any potential overlap with the original. It is EPA's most basic job to evaluate the implications of its actions, yet this most basic of obligations is an abject cipher here.

Strikingly, EPA offers *no* rationale for expanding the scope of its prohibitions to influential scientific information.[264] The closest the agency comes to an explanation is a passing reference to OMB implementation updates recommending that "[a]gencies should prioritize increased access to the data and analytic frameworks (*e.g.*, models) used to generate influential information."[265]

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[261] EPA, Peer Review Agenda, https://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

[262] Perchlorate is a highly toxic compound that interferes with normal functioning of the thyroid gland. *See* Tox Town, U.S. National Library of Medicine, Perchlorate, https://toxtown.nlm.nih.gov/chemicals-and-contaminants/perchlorate; EPA, Perchlorate in Drinking Water Frequent Questions, https://www.epa.gov/sdwa/perchlorate-drinking-water-frequent-questions#where-found.

[263] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

[264] *See* 85 Fed. Reg. at 15,398.

[265] *Id.* at 15,402.

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OMB does not suggest that an agency should disregard data and analytic frameworks in developing influential information. Absent any rationale for expanding the scope of its rule to influential scientific information, finalizing the Supplemental Notice would be arbitrary.[266]

* * *

Multiplying these expansions together, all data and models used in pivotal science or pivotal regulatory science, results in a dramatic and even more untenable imposition on the scientific work of the agency with dramatic implications for public health and environmental protection. Section IV.A.1 of these comments provide specific—though by no means comprehensive—applications of these expansions in practice. Ultimately, the indeterminate and unexplained expansion of the Supplemental Notice means that many more high quality studies would be disqualified from full consideration and utilization by the agency unless the underlying data are publicly available,[267] and this phenomenon would occur more often as the agency imposes the proposal's requirements on many more scientific products of the agency. As a result, the scientific rigor and merit of the agency's work would diminish substantially, and with it a failure to adhere to statutory obligations to use the best available science and all available data as well as a failure to protect public health and the environment.[268] More foundationally, EPA continues to fail to articulate the problem it seeks to solve or identify any benefits the proposal would yield.[269]

B. EPA Fails to Acknowledge or Examine the Disastrous Effect of Further Decreasing the Quantity of Studies upon Which It Can Base Its Regulatory Decisions and Influential Scientific Information.

In addition to providing an inadequate description and justification for the proposed expansions, as noted in Section IV.A, EPA has failed to examine the sweeping effects of expanding coverage of the rule to all data and models and to influential scientific information. At a basic level, expanding the requirement for disclosure of all variety of underlying data and models increases the chances that EPA will ignore any given study—even those that include dose-response data and models that have been disclosed per the proposal's requirements, if such studies include other forms of data and models that remain unavailable. It also sweeps in studies that do not examine dose-response relationships at all. EPA has not estimated the proportion of valid, relevant

[266] *See State Farm*, 463 U.S. at 48-49, 55-57; *Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *19 ("It is axiomatic that the APA requires an agency to explain its basis for a decision.").

[267] For discussion of the problems with the tiered access and differential weighting approaches, *see* Section V, *infra*.

[268] *See* Section III.A, *supra*.

[269] *See* Section I, *supra*.

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research that it would disregard under the expanded proposal.[270] As discussed in EDF's comments on the original proposal, the Congressional Budget Office has estimated the number of studies that legislative proposals similar to EPA's rule would affect, both overall and at the level of individual actions, such as reviews of the NAAQS.[271] EPA presumably has better information than CBO does about the volume of scientific information it relies on across its programs; indeed, CBO relied on information from EPA on how the agency would implement the legislation, as well as the cost of complying with it, in developing the CBO estimate.[272] Using updated information, EPA must conservatively estimate both the absolute numbers and the proportion of studies it would rule out through this proposal—overall and in each foreseeable individual action—reasonably assuming that tiered access and de-identification are not feasible. Similarly, the agency must conservatively estimate the number of studies that would be given lesser consideration under the alternative approach described in the proposal. The omission of any such analyses renders its rule arbitrary.[273]

At a higher level, EPA has failed to acknowledge or examine the impacts of expanded coverage on its own rulemakings. The problem is not merely additive; some of the actions that EPA intends to cover with this rule, such as integrated science assessments that inform national ambient air quality standards (NAAQS), are based on an assessment of overall confidence in an at-risk factor (i.e., a factor that potentially increases the risk of air-pollutant related health effects for individuals in certain subpopulations), and excluding one or more studies showing a relationship between that factor and adverse health effects could tip the balance toward, for example, recommending a change in the NAAQS.[274] Thus, arbitrarily ignoring rigorous studies at one or multiple stages of the regulatory process could alter critical health and environmental protections and would be illegal.[275]

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[270] *See* Final SAB Report at 15 ("It is not clear: (1) how many of the studies EPA currently relies upon to take important regulatory actions would meet the public disclosure standards stated in the Proposed Rule, and (2) . . . what the impact of precluding . . . studies would be on EPA's decision making and its ability to protect public health/environment.").

[271] *See* Jon Sperl & Amy Petz, Cong. Budget Office, Cost Estimate for H.R. 1430: Honest and Open New EPA Science Treatment (HONEST) Act of 2017 at 2-3 (Mar. 29, 2017) ("CBO Estimate for H.R. 1430"); CBO Estimate for S. 544, *supra* note 4, at 2-3.

[272] *See* CBO Estimate for H.R. 1430, *supra* note 271, at 2-3.

[273] *See State Farm*, 463 U.S. at 43 ("Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem."); *Process Gas Consumers Grp. v. USDA*, 694 F.2d 778, 790-91 (D.C. Cir. 1982) (en banc) (faulting FERC for failing to "assess the consequences of fully incorporating a current requirements methodology" in implementing USDA's certification of essential agricultural uses of natural gas).

[274] EPA, Preamble to the Integrated Science Assessments at 25-27 (Nov. 2015).

[275] *See, e.g.*, *U.S. Air Tour Ass'n v. FAA*, 298 F.3d 997, 1013, 1018-19 (D.C. Cir. 2002) (invalidating the FAA's decision to ignore noise from non-tour aircraft over national parks, when the agency had "given every indication it w[ould] employ [the decision] in future rulemakings").

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Moreover, the expanded proposal would irreconcilably conflict with EPA's obligation to regulate emissions of hazardous air pollutants under the Clean Air Act. Section 112 of the Act requires EPA to set emission standards for existing major sources of hazardous air pollutants that are typically no less stringent than "the average emission limitation achieved by the best performing 12 percent of the existing sources (for which the Administrator has emissions information)."[276] This provision does not allow EPA to ignore information that the agency possesses but that qualifies as confidential business information. Indeed, EPA has historically taken such confidential business information into account in calculating the minimum limitation.[277] Now, however, EPA has proposed to define "data and models" to encompass "data on environmental releases" and to eliminate any such data that would underlie pivotal regulatory science driving the level of a standard, such as emission standards under section 112.[278] EPA's proposed rule, as expanded, patently conflicts with the Clean Air Act's well established requirements and cannot be finalized.[279]

By expanding the scope of its 2018 proposal, EPA has also inadvertently and irrationally hampered its ability to cooperate with other agencies in conducting joint or coordinated rulemakings, beyond the examples noted previously.[280] For example, EPA recently finalized emission standards for greenhouse gases from light-duty vehicles, which it intended to harmonize with the National Highway Traffic Safety Administration's (NHTSA) corporate average fuel economy standards (CAFE). Both sets of standards are based on scientific analysis for which underlying data or models are not available.[281] EPA could not have relied on this analysis in setting greenhouse gas standards had the proposal's requirements been in place, even if the analysis did not alter the level of the standards.[282] Presumably, however, there would be instances in which

[276] 42 U.S.C. § 7412(d)(3)(A).

[277] *See, e.g.*, 67 Fed. Reg. 46,028, 46,044-45 (July 11, 2002); 63 Fed. Reg. 68,832, 68,843, tbl. 4 (Dec. 14, 1998).

[278] *See* 85 Fed. Reg. at 15,401-02; 83 Fed. Reg. at 18,773 (proposed 40 C.F.R. § 30.2, defining "[p]ivotal regulatory science").

[279] For the reasons discussed above, *see* Section III.C, *supra*, EPA's promise to yield in its application of the proposed rule whenever clear statutory duties require it to consider otherwise off-limits information cannot cure the rule's fundamental defects. On the contrary, the proposal's incompatibility with a wide array of EPA's governing statutes provides further evidence that the proposal is arbitrary and unlawful.

[280] *See* EDF 2018 Comments at 80-81.

[281] *See, e.g.*, The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021-2026 Passenger Cars and Light Trucks, 85 Fed. Reg. 24,174, 24,551 (Apr. 30, 2020) (noting that the agencies modeled aerodynamic improvement technologies partly "based on confidential business information submitted by the manufacturers"); *see also id.* (using updated cost estimates from the National Academy of Sciences in the same modeling).

[282] *See* 83 Fed. Reg. at 18,773 (defining "[p]ivotal regulatory science" as "the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions" (emphasis added)); *see also* 85 Fed. Reg. at 24,271 ("The purpose of the analysis is not to determine the standards, but rather to provide information for consideration in doing so.").

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discrepancies in the rulemaking records considered by EPA and NHTSA, respectively, would result in different standards. It would be bizarre if, going forward, EPA and NHTSA were to attempt another harmonized rulemaking and be prevented from doing so by the fact that NHTSA relied on studies without publicly available underlying data or models while EPA would not.

Relatedly, the proposal could impede any EPA rulemaking, or joint rulemaking, for which the National Environmental Policy Act (NEPA) requires an environmental impact statement (EIS). The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule is a case in point. There, NHTSA prepared an EIS examining the emissions, air quality, and health impacts of weakening fuel economy standards, with EPA as a cooperating agency in the preparation of the EIS. NHTSA averred that it prepared the EIS "[t]o inform its development of the final CAFE standards."[283] Thus, to the extent that EPA's GHG standards in the SAFE Vehicles Rule conform to NHTSA's CAFE standards in the same joint rule, the studies considered in the EIS also qualify as "pivotal regulatory science" that "drive[s] the requirements and/or quantitative analysis of [an] EPA final significant regulatory decision."[284] NEPA requires the agency to take a "hard look" at the relevant data and, in some cases, gather more data.[285] At the very least, the agency must explain why data it omitted "would not alter its conclusions in the EIS or the approval of [the action]."[286] The proposal here would summarily rule out data that NEPA requires the agency to include and consider in an EIS.

V. BOTH OF THE SUPPLEMENTAL NOTICE'S ALTERNATIVE OPTIONS ARE ARBITRARY AND UNLAWFUL

The Supplemental Notice offers two alternative approaches that would theoretically allow EPA to consider studies for which underlying data or models are not or cannot be made publicly available. The first provides for tiered access to data or models underlying studies; the second provides for differential weighting of studies based on the extent to which their underlying data or models are publicly available.[287]As with the original proposal, both approaches violate multiple statutory requirements to use the best available science and to consider all available data.[288] Both approaches would *a priori* unjustifiably require or allow the agency to ignore or give less weight

[283] NHTSA, SAFE Rule for Vehicles Rule for Model Year 2021–2026 Passenger Cars and Light Trucks Final Environmental Impact Statement S-1 (Mar. 2020); *see also Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 100 (1983) ("As a general proposition, we can agree with the Court of Appeals' determination that an agency must allow all significant environmental risks to be factored into the decision whether to undertake a proposed action.").

[284] 83 Fed. Reg. at 18,773 (proposed 40 C.F.R. § 30.2).

[285] *Pub. Employees for Envtl. Responsibility v. Hopper*, 827 F.3d 1077, 1083 (D.C. Cir. 2016).

[286] *Vill. of Bensenville v. FAA*, 457 F.3d 52, 71 (D.C. Cir. 2006).

[287] 85 Fed. Reg. at 15,405.

[288] *See* Section III.A, *supra*; *see also* EDF 2018 Comments at 14-34.

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to studies based on whether underlying data or models are available for reanalysis—an arbitrary criterion that ignores the rigor and validity of a study, as well as its usefulness for agency decision-making.

As discussed above, EPA has embarked on an expedition to solve a non-existent problem, and it has wandered far off-course by proposing to ignore studies for which underlying data and models are not publicly available. EPA acknowledges "a large number of comments stating that the approach in the 2018 proposed rulemaking would likely preclude the use of valid data and models from consideration as pivotal regulatory science," an error that prompted the Supplemental Notice.[289] Yet the revised approach perpetuates this problem: it continues to exclude or devalue valid studies solely because the underlying data and models are not publicly available. The Supplemental Notice therefore remains arbitrary for the reasons detailed in comments on the original proposal and summarized here.

Public availability of data is not synonymous with reliability: researchers do not make data public to improve the strength or quality of their findings, and EPA has offered no evidence to suggest that studies with publicly available underlying data are more likely to represent strong science than studies without such data availability.[290] Although reanalysis of data may help confirm a study's results, it is not a primary or sufficient way to validate those results.[291] Rather, the scientific community more heavily relies on peer review and reproducing results[292] using different populations or methods to validate findings.[293] EPA has used such means to ensure the studies it relies on are valid, including comparison of findings with the results of other research and strong peer-review processes led by scientific journals, EPA, or advisory bodies such as the SAB.[294] EPA now refuses to acknowledge these proven and preferred methods, while clarifying that its rule would not actually require any reanalysis of data before the agency uses a study.[295]

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[289] 85 Fed. Reg. at 15,401-02.

[290] EDF 2018 Comments at 73.

[291] *Id.*

[292] As described in a workshop report of National Academies of Sciences, Engineering, and Medicine, "when you *reproduce*, you are producing something that is very similar to that research, but it is in a different medium or context . . . . In other words, a researcher who is reproducing an experiment addresses the same research question but from a different angle than the original researcher did." Nat'l Acads. of Sci., Eng'g, & Med., *Principles and Obstacles for Sharing Data from Environmental Health Research: Workshop Summary*, at 6 (2016) (emphasis in original) (internal quotations omitted), available at https://doi.org/10.17226/21703. We note that this report is merely a summary of a workshop convened by the National Academies and does not reflect the views of the National Academies itself.

[293] EDF 2018 Comments at 74-75.

[294] *Id.* at 71-73.

[295] 85 Fed. Reg. at 15,402.

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Inexplicably, however, it insists on excluding or devaluing studies for which the underlying data are not available.

Exacerbating the fundamental flaw of continuing to disregard whole swaths of current and future research, the agency's proposed solutions do nothing to allow rigorous consideration of the vast body of historical studies that document the harm that pollutants cause to human health and welfare. EPA acknowledges objections to the original proposal's exclusion of "many older studies" that include valid data and models.[296] The Supplemental Notice does not, however, respond to these concerns. As explained above, both the tiered access approach and the differential weighting approach would apply retroactively to data and models finalized prior to the rule's effective date unless the Administrator grants a case-by-case exemption.[297] Yet, as EPA admits, there are compelling reasons why it may be impossible or infeasible to provide access to data and models underlying older studies.[298] The revised and alternative approaches therefore fail to address one of the most substantial shortcomings of the original proposal—one that EPA has explicitly acknowledged in its Supplemental Notice.[299]

Ultimately, both approaches fail to address numerous concerns and conflicts raised in EDF's comments submitted on the original proposal regarding scientific principles and practices associated with evaluation of study quality and integration of evidence.[300] Of note, in proposing these alternative options, EPA continues to ignore well-established practices effectively used in the scientific community to vet research, opting instead to discard research that does not meet its disclosure requirements.[301] Finally, neither option addresses fundamental concerns raised about the original proposal regarding cost, ethics, and feasibility of disclosing data and models.

[296] 85 Fed. Reg. at 15,401-02.

[297] *See* Section I.E, *supra*.

[298] *See* Section I.E, *supra*.

[299] 85 Fed. Reg. at 15,403.

[300] *See, e.g.*, EDF 2018 Comments at 64-79.

[301] *See* Section I.B, *supra*; *see also* Final SAB Report at 17 ("The EPA, [OMB], and scientific institutions have . . . recognized that . . . constraints on availability of data do not prevent studies from being verified in other ways - or preclude those studies from being considered in regulatory decisions." (citing EPA and OMB policy documents, as well as a letter from the presidents of the National Academies to EPA regarding this rulemaking)).

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A. Both the Tiered Access and Differential Weighting Approaches Would Result in Arbitrary Exclusion of the Best Available Science.

1. Relevant Studies Would Be Excluded from Consideration by the Agency Under the Tiered Access Approach.

The tiered access approach would still require that all data and models underlying studies be made publicly available with a provision that for studies "with restricted data and models (i.e., those that include confidential business information (CBI), proprietary data, or Personally Identifiable Information (PII) that cannot be sufficiently de-identified to protect the data subjects)," different tiers of access be available to such underlying data and models where more restricted access occurs for more sensitive data and models.[302] While this approach provides for different degrees of access to underlying data and models, the expectation is that all underlying data and models must be available even if under restricted access. As such, EPA's proposal would still ultimately exclude relevant studies from consideration in the development of influential scientific information and significant regulatory decisions unless their underlying data and models are fully available to EPA and those who have been granted access. These exclusions would continue to be arbitrary for reasons discussed at length in Sections I and IV of these comments and Section II of EDF's 2018 comments.

In altering its proposed approach, EPA purports to address objections to the agency's exclusion of valid data and models containing confidential, proprietary, or personal data that cannot be sufficiently de-identified to protect data subjects.[303] Yet EPA's tiered access approach is an inadequate response to these objections. If tiered access does not exist, for whatever reason, the agency will ignore all studies for which data and models are not publicly available.[304] Thus, the tiered access modification to the original proposal fails to cure its essential defect: the agency would continue to disregard valid studies without any rational grounding in its statutory authorities, and in plain violation of numerous statutory requirements.[305]

2. Relevant Studies Would Be Arbitrarily Undervalued or Excluded Under the Differential Weighting Approach.

Under the differential weighting approach, EPA is proposing to devalue or exclude studies if their underlying data and models are not publicly available, or are not fully available via a tiered

[302] 85 Fed. Reg. at 15,399, 15,405.

[303] *Id.* at 15,402.

[304] *Id.*

[305] *See* EDF 2018 Comments at 13-94.

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access approach. As with the tiered access approach, this requirement would lead to a failure by the agency to use the best available science and consider all available information, in violation of EPA's statutory obligations.[306]

EPA's differential weighting approach would therefore fail to solve the original proposal's fundamental problem. The agency suggests that, while it would give greater weight to studies for which underlying data and models are available (possibly through tiered access), it "*may* still consider studies where there is no access or limited access to underlying data and models."[307] The agency's consideration of relevant, valid studies is not optional.[308] Moreover, EPA indicates the agency could downgrade its consideration of many valid studies, seeking input on how much to diminish their weight.[309] Discarding or discounting otherwise valid studies, for no reason other than an *a priori* judgment made without regard to study quality, is arbitrary and illegal, for the same reason that disregarding such studies altogether is illegal.

B. THE TIERED ACCESS APPROACH IS UNEXPLAINED AND ARBITRARY.

EPA's preferred approach, which "would allow Agency consideration of studies where there is tiered access to data and models," is arbitrarily vague and notional.[310] EPA observes, generally, that:

> Under a tiered approach to accessing data and models . . . access is more restricted for more sensitive data and models. Thus, the amount of information available for analysis is dictated by the tier. The greatest amount of information is made available at the most restricted access tier.[311]

Nowhere does the agency specify the types of data and models it envisions would be encompassed by each tier, or even how many tiers might exist. Regarding potential requirements to gain access, EPA speculates:

> Restricted access for researchers through secure data enclaves for [personally identifiable information] or through non-disclosure agreements for [confidential

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[306] *Id.*

[307] 85 Fed. Reg. at 15,402 (emphasis added).

[308] *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018).

[309] *See* 85 Fed. Reg. at 15,403 ("EPA is also requesting comment on how much consideration should be given to studies when there is limited or no access to the underlying data and models.").

[310] 85 Fed. Reg. at 15,402.

[311] *Id.*

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> business information] may result in access to sufficient information about the data and models to allow for independent validation."[312]

The agency does not actually propose either secure data enclaves or non-disclosure agreements—or any other specific arrangement—as a mechanism to implement its preferred approach in the Supplemental Notice. On the contrary, its discussion underscores that EPA is unable to effectuate or define the tiered-access approach. For example, EPA notes that it is "currently conducting a pilot study using the [Research Data Center's] secure data enclave to host EPA datasets in a restricted use environment," access to which is limited to researchers who "submit a research proposal outlining the need for restricted-use data."[313] EPA does not describe any results from its pilot study, nor does it propose any criteria that it would use to evaluate requests for access to a secure data enclave. Similarly, the agency observes that the White House Office of Science and Technology Policy has an open solicitation for comment that could "help federal agencies provide more consistent information on desirable characteristics of data repositories."[314] Yet EPA has not provided any such information here. In fact, EPA's recent briefing to House Science, Space, and Technology Committee staff reveals that the agency remains in utter disarray as to the management of one or more outside enclaves, hypothetically by unspecified third parties or other federal agencies not involved in this rulemaking.[315] This persistent disregard of a key aspect of the agency's preferred approach renders the proposal arbitrary and unlawful.[316] It also prevents the public from meaningfully commenting on the practical feasibility, costs, and impacts of the agency's proposed approach.

Specifically, EPA fails to provide sufficient description or necessary analysis of the agency's envisioned tiered access approach including details relating to the determination of tiers; procedures for granting access to various tiers of data; operation, curation, management and oversight of data repositories; data repository ownership; whether, and if so, how repositories involving personally identifiable information and confidential business information could be legal; safeguards to prevent hacking of web-based repositories; liability implications for researchers handling personally identifiable information or confidential business information; considerations relating to the extent to which study authors would participate generally; and costs.

Instead, EPA's description of a tiered access approach is cursory and comprised of meaningless generalities. For example, regarding protection of personally identifiable information,

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[312] *Id.*

[313] *Id.*

[314] *Id.*

[315] Memo to Chairwoman Johnson, *supra* note 120, at 2.

[316] *State Farm*, 463 U.S. at 43.

EPA merely states that "[a]ccess to data involving [personally identifiable information] would be consistent with the requirements of the Common Rule, the Health Insurance Portability and Accountability Act (HIPPA) [sic], the 21st Century Cures Act, the Privacy Act, and other relevant laws and regulations, and EPA privacy policies."[317]

The closest EPA comes to describing its envisioned tiered access approach is a brief reference to the Research Data Center (RDC), National Center for Health Statistics (NCHS), Centers for Disease Control (CDC).[318] The RDC houses various health data relating to population health, vital records, and healthcare records among other information. EPA's reference to the RDC is wholly inappropriate, as the data features are entirely different from the scope of scientific information EPA is capturing in the Supplemental Notice. The data housed within the RDC are either developed directly by the federal government or collected through federal government-designed and managed programs. These data are highly standardized, and the platforms housing the data are developed and managed by the government. In other words the RDC is a highly controlled, integrated, and coordinated data infrastructure. In contrast, EPA's proposal targets all potential "data and models" to be considered by the agency that are developed by a wide breadth of entities inside and outside government and that are highly variable including in terms of how they are generated, collected, curated, and stored. Furthermore, EPA is entirely silent on who or what entity will create and manage the tiered access approach. EPA certainly doesn't suggest that it will. Any reference to the RDC as an analogous potential model for EPA's tiered access approach is highly inappropriate and disingenuous.

The SAB has identified similar problems with the proposed rule:

> Some individual data (i.e., data associated with individuals in a sample) used in epidemiological studies are held by federal agencies such as the Centers for Disease Control and Prevention or the Department of Health and Human Services (Medicare data), while other data have been developed by state, local or tribal governments, academic institutions or private organizations, among others. Some federal agencies have efficiently developed methods for making data available to the public (e.g., Census Bureau, CDC). *Currently, no comparable system exists for datasets that are owned by non-federal governments (e.g., states, tribes), and/or owned by private societies/organizations or academic institutions, which are themselves protected by strong privacy and confidentiality requirements through their Institutional Review Boards (IRBs).* . . .

[317] 85 Fed. Reg. at 15,402.

[318] *Id.*

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> The proposed regulation should clearly address the issue of obtaining public access to datasets while maintaining the privacy of the participants and confidentiality of the data, because without such access, sensitive data and confidential business information could be excluded entirely from consideration as pivotal regulatory science.[319]

Plainly, the Supplemental Notice—which the SAB has considered—does not even begin to address this fundamental inadequacy. Without any specific proposals as to how it would implement its preferred tiered access approach, EPA has failed to provide the requisite notice.[320]

The vagueness of the tiered access approach, if finalized, would render it arbitrary for another reason as well: researchers whose work is relevant to the regulatory process would no longer be able to pursue studies to ensure that EPA could consider their findings. By replacing its prior policy of considering peer reviewed studies with a prerequisite of indeterminate "tiered access" to data and models, the agency has disregarded these stakeholders' reliance interests in a predictable system for accepting and considering scientific information. EPA has failed to provide the more detailed justification necessary for altering its policy in a way that would inject uncertainty into policy-oriented scientific inquiry.[321]

Even presuming some semblance of a defined approach, EPA fails to assess the legal and practical barriers to implementing tiered access. Regarding personally identifiable information, the agency observes:

> Access to data involving [personally identifiable information] would be consistent with the requirements of the Common Rule, the Health Insurance Portability and Accountability Act (HIPPA) [sic], the 21st Century Cures Act, the Privacy Act, and other relevant laws and regulations, and EPA privacy policies. Reanalyzing findings of studies based on data and models that include PII (*e.g.*, residence) or CBI may not be possible given the degree of perturbation caused by deidentification that would be needed for the information to be made publicly available.[322]

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[319] Final SAB Report at 3 (emphasis added).

[320] *See Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 549 ("Agency notice must describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decisionmaking."); *see also id.* ("This is doubly true under Clean Air Act § 307(d)(3), which requires EPA to issue a specific 'proposed rule' as a focus for comments.").

[321] *Cf. Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1114 (D.C. Cir. 2019) (noting that the agency had failed to take into account the reliance interests of certain telecommunications providers and their customers, who could lose access to service).

[322] 85 Fed. Reg. at 15,402.

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Nowhere does EPA explain how it would ensure compliance with such statutory requirements or evaluate the extent of the restrictions they might place on its tiered access approach. As for confidential business information, EPA points to its existing regulations on disclosure of CBI as a potential framework that would govern tiered access to such information.[323] Those regulations, however, provide a detailed process for applying the rules and adjudicating disputes as to confidentiality, and EPA has not demonstrated that the agency has the capacity to administer a system of tiered access to the myriad studies that support all of its regulatory decisions and influential scientific information.[324] In sum, EPA has arbitrarily offered no explanation of how and to what extent legal restrictions on the sharing of confidential information would impede its preferred "tiered access" approach.[325]

EPA also failed to consider the likelihood that tiered access would not be practical or ethical if study participants did not consent to their personal information being examined by outside parties, even with restrictions. Several members of the SAB expressed concerns along these lines.[326] The SAB expressed a similar concern in its majority report on the proposed rule:

> It may not be feasible to identify and make available data in epidemiological studies that arise from small datasets or targeted geographic areas, especially if the Informed Consent Form indicated that only the particular researchers who conducted the study would have access to the information and data. If the participants agreed to grant only a select group of researchers access to their personal information, then that consideration should be respected, and such information should not be supplied to additional people for validation. It would probably be impractical, to go back to the participants and request their approval to provide additional people access to personal information.[327]

It would be arbitrary for EPA to ignore this important aspect of the problem,[328] especially in disregarding the comments of its own science advisers on these issues.[329]

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[323] 85 Fed. Reg. at 15,402-03.

[324] *See* 40 C.F.R. §§ 2.204, 2.205.

[325] *Cf. Am. Pub. Power Ass'n v. Fed. Power Comm'n*, 522 F.2d 142, 146 (D.C. Cir. 1975) (upholding a rule for which the Commission explained how it would address antitrust implications).

[326] *See* SAB Consultation at B-10 (statement of Dr. Janice Chambers); *id.* at B-28 (statement of Dr. Kenneth M. Portier); *see also id.* (noting that owners of data may be unwilling to submit the data to a repository with tiered access).

[327] Final SAB Report at 10.

[328] *State Farm*, 463 U.S. at 43.

[329] *See, e.g., NRDC v. EPA*, 808 F.3d 556, 570-71 (2d Cir. 2015).

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Indeed, an underlying assumption of the tiered access approach is that researchers involved in the development of pivotal science or pivotal regulatory science will participate, and EPA has provided no analysis indicating the extent to which the agency believes compliance could or would occur. Instead, it is reasonable to assume that many researchers would not engage in a tiered access approach for a variety of reasons, the significant anticipated costs being just one for which EPA has utterly failed to provide any analysis.[330] As mentioned earlier, this outcome would likely lead to the exclusion of studies representing the best available science, and a failure on EPA's part to consider all relevant information.

Finally, EPA has completely disregarded the potential for pro-industry bias by considering studies for which interested parties have arranged for tiered access. EPA's recent briefing to House Science, Space, and Technology Committee staff underscores how the tiered access approach would preference industry interests: researchers would be responsible for managing the logistics of making data and models publicly available and establishing levels of tiered access;[331] a time-consuming and labor-intensive process for investigators who have already concluded their work and published their findings, possibly having expended the full amount of funding available, unless specially interested third parties bankroll the process.[332] Once established, tiered access would also allow financially interested, repeat players such as regulated entities to test the findings of whatever studies they dislike. EPA has thus proposed to establish a requirement that would favor industry interests by compelling disclosure of data and methods that regulated entities can more readily furnish and that only regulated entities will likely have the resources and motivation to scrutinize with any frequency. Such favoritism in the agency's rule would be arbitrary unless somehow grounded in its authorizing statutes.[333] At the very least, EPA would need to assess, consider, and balance the substantial unfair advantage industry would receive against any theoretical, marginal increase in the reliability of scientific information that could result from a tiered access approach. EPA has completely ignored the issue here, yet another reason that it cannot finalize the Supplemental Notice.

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[330] *See* Section I.D, *supra* (noting recent comments on the challenges of establishing and participating in a tiered access system, for both the original researchers and subsequent investigators).

[331] Memo to Chairwoman Johnson, *supra* note 120, at 2.

[332] *See* SAB Consultation at B-25 (comments of Robert W. Merritt).

[333] *See Cent. Fla. Enters., Inc. v. FCC*, 598 F.2d 37, 41 (D.C. Cir. 1978); *cf. Action for Children's Television v. FCC*, 564 F.2d 458, 480 (D.C. Cir. 1977) (upholding a rule against a claim of pro-industry bias); *see also Am. Trucking Ass'ns, Inc. v. EPA*, 175 F.3d 1027, 1052-53 (D.C. Cir. 1999), *rev'd on other grounds sub nom. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001) (concluding it was arbitrary for EPA to disregard study based on informational criteria not applied to other such studies).

C. THE DIFFERENTIAL WEIGHTING APPROACH IS ALSO UNEXPLAINED AND ARBITRARY.

As with the tiered access approach, EPA provides no details as to how the differential weighting alternative approach would work in practice. Rather, EPA merely states:

> [W]hen promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will, other things equal, give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation either because the information is publicly available or available through tiered access when the data include CBI, proprietary data, or PII and appropriate techniques have been used to reduce the risk of re-identification. In developing the significant regulatory decision or influential scientific information, the EPA will identify those studies that are given greater consideration and provide a short description of why greater consideration was given. However, the Agency may still consider studies where there is no access or limited access to underlying data and models.[334]

This description is entirely ambiguous, lacking sufficient detail not only as to how EPA would intend to apply this alternative approach in practice (including how much weight it would give to the availability of data and models in assessing studies), but also under what circumstances the agency would or would not decide to apply this alternative approach as EPA maintains it *may* consider studies where underlying data is not available or only available on a limited basis.[335] In EPA's briefing to House Science, Space, and Technology Committee staff, the agency "was unable to expand on how this potential weighted system would operate. The Agency has not identified implementation details for the weighting approach, including any concrete ideas about how the scale of a weighted system would be structured."[336] The fact that EPA itself does not understand how the alternative would work confirms that the agency has not provided adequate notice for public comment,[337] and it cannot finalize any such alternative without first examining the details of its implementation.[338]

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[334] 85 Fed. Reg. at 15,402.

[335] EPA's suggestion that there will be instances where studies will be "equal" with the exception of the availability of underlying data is entirely disingenuous. In reality, underpinning influential scientific information and significant regulation, will be a diverse body of evidence of different methodological design and no two studies will be exactly alike with exception of data availability. EPA's suggestion that this will be the case may be convenient, but in no way reflects the realities of research and science.

[336] Memo to Chairwoman Johnson, *supra* note 120, at 4.

[337] *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 518-19, 549-50.

[338] *State Farm*, 463 U.S. at 43.

Aside from the vagueness of the weighting approach, EPA has also failed to explain how differential weighting of studies based on data availability adds to, modifies, or is needed in light of existing, relevant frameworks at the agency including, for example, frameworks developed for EPA Integrated Risk Information System (IRIS) toxicological reviews,[339] the development of Integrated Science Assessments,[340] and ecological assessments.[341] More broadly, implicit in EPA's differential weighting approach is an indication that the availability of underlying data in and of itself is an indicator of study quality such that this feature alone can determine the weight a study is given within a body of evidence. In fact, EPA has failed to provide any empirical evidence supporting a relationship between data availability and study quality or reliability. Meanwhile, study evaluation criteria used in leading systematic review frameworks that have been developed for environmental health, such as the University of California San Francisco Navigation Guide[342] and the U.S. Toxicology Program Office of Health Assessment and Training systematic review handbook,[343] have been adapted from prominent systematic review methods in medicine, namely the Cochrane Reviews.[344] Cochrane Review study evaluation criteria have been developed and refined over decades, and are supported by empirical evidence[345] and experience in application.[346] In contrast, EPA's failure to provide any factual support for assigning the availability of underlying data controlling weight in its assessment of studies renders the proposal arbitrary.[347]

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[339] *See, e.g.*, EPA, *IRIS Systematic Review Protocol for Polychlorinated Biphenyls (PCBs)*, https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=237359.

[340] EPA, *Preamble To The Integrated Science Assessments (ISA)*, EPA/600/R-15/067 (2015), https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244.

[341] EPA, Risk Assessment Forum, *Weight of Evidence in Ecological Assessment*, EPA/100/R-16/001 (2016), https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/3839851.

[342] Tracy J. Woodruff, & Patrice Sutton, *The Navigation Guide Systematic Review Methodology: A Rigorous and Transparent Method for Translating Environmental Health Science into Better Health Outcomes*, 122 Envtl. Health Persp. 1007 (2014), https://ehp.niehs.nih.gov/doi/10.1289/ehp.1307175.

[343] Nat'l Toxicology Program, *Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration* (2019), https://ntp.niehs.nih.gov/whatwestudy/assessments/noncancer/handbook/index.html.

[344] Cochrane Database of Systematic Reviews, https://www.cochranelibrary.com/cdsr/about-cdsr (last visited May 15, 2020).

[345] Cochrane, *Revised Cochrane Risk-of-Bias Tool for Randomized Trials (RoB 2)* (Julian Higgins et al. eds., 2019), https://www.researchgate.net/profile/Prachi_Kaistha/post/Do_we_have_the_option_to_choose_one_of_the_two_effects_ITT_and_Per-Protocol_Effect_in_the_New_Cochrane_Risk_of_Bias_Tool_20/attachment/5e9a06d94f9a520001e08c5b/AS%3A881396046393349%401587152601564/download/20190822_RoB_2.0_guidance_parallel_trial.pdf.

[346] *Cochrane Handbook for Systematic Reviews of Interventions*, § I.1.1 (Julian Higgins et al. eds., Version 6, 2019), https://training.cochrane.org/handbook/current/chapter-i#a-i11-a-brief-history-of-cochrane.

[347] *State Farm*, 463 U.S. at 43.

EPA departs without explanation or acknowledgement from its existing, well-established approaches for assessing the weight of scientific evidence. For example, its Risk Assessment Forum recommends weighting evidence based on relevance, strength, and reliability.[348] Even within reliability, the Forum observes that "scoring the most important component properties" is useful.[349] Transparency is only one such component, and it is merely "*presumed* to increase reliability by reducing the likelihood of hidden faults."[350] EPA offers no reason to give overwhelming importance to one component of reliability in this framework, and, in turn, to reliability over the strength and relevance of a study. In fact, EPA does not discuss existing approaches to weighting evidence at all. EPA has therefore failed to acknowledge that it is changing policies or to provide a good reason for doing so, rendering a final rule that is similarly deficient and unlawful.[351]

With its differential weighting approach, EPA is opting to give substantial weight to data availability relative to other more powerful indicators of study quality including its actual methodological design or the extent to which a study's general findings and conclusions have been corroborated in different studies employing different data or different methodologies. EPA's proposal is at odds with scientific best practices.

VI. EPA'S NEW DEFINITIONS ARE INADEQUATE AND INACCURATE

The definitions EPA proposes are again confusing and fail to match established scientific terminology, including the use of those terms reflected in some of the primary references cited in the Supplemental Notice.[352] Concerns with EPA's definitions are discussed below.

- Capable of being substantially reproduced. EPA proposes to define "capable of being substantially reproduced" to "mean[] that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error."[353] This definition represents an attempt to, once again, bring the word *reproduced* into the realm of *reanalyzed*.

[348] *See* EPA, *Weight of Evidence in Ecological Assessment*, *supra* note 341, at 27.

[349] *Id.* at 33.

[350] *Id.* at 34 (emphasis added); *see also id.* at 36 ("Reliability has at least 11 component properties that are conceptually distinct, ... and more than one can be applied to a piece of evidence.").

[351] *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *22-28.

[352] *See, e.g.*, 85 Fed. Reg. at 15,400 (citing Nat'l Acads. of Sci., Eng'g, & Med., *Principles and Obstacles for Sharing Data from Environmental Health Research: Workshop Summary* (2016)).

[353] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

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As EDF discussed in its comments on the original proposal:

> *[W]hen you **reproduce** a scientific experiment, you are producing something that is very similar to that research, but it is in a different medium or context. For example, a researcher who is reproducing an experiment addresses the same research question but from a different angle than the original researcher did.*[354]

and

> *A **reanalysis** is when you conduct a further analysis of data. A person doing a reanalysis of data may use the same programs and statistical methodologies that were originally used to analyze the data or may use alternative methodologies, but the point is to analyze exactly the same data to see if the same result emerges from the analysis.*[355]

EPA's proposed definition for "capable of being substantially reproduced" attempts to make "reanalysis" synonymous with "reproduce," which is wholly inappropriate. To use the term "reproduced" in this context is to mislead the public into believing that some new scientific insights have been applied to an original set of data such that the original research findings are made stronger.

Rather, EPA's definition for "capable of being substantially reproduced" highlights a fundamental misconception underpinning the premise of the proposal—that somehow independent validation is accomplished through reanalysis of study data by other experts. In fact, the strength of scientific findings are not determined by endless reanalysis of a single data set, but rather gained over time through the conduct of separate investigations utilizing different methodologies that yield corroborating conclusions around a hypothesis being explored.

- Data. EPA provides the following proposed regulatory definition for "data":

> [T]he set of recorded factual material commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as keystroke or coding errors, have been removed and that is capable of being analyzed by either the original researcher or an independent party.[356]

[354] EDF 2018 Comments at 10.

[355] EDF 2018 Comments at 9.

[356] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

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Here again the definition of "data" is tied to the concept of reanalysis rather than the more common definition from Merriam-Webster: "[F]actual information (such as measurements or statistics) used as a basis for reasoning, discussion, or calculation."[357] EPA assumes that this is the "data" that is "necessary to validate research findings." Validation of a research finding involves a determination of whether the scientific findings are *well-grounded, sound and correct*—a much broader inquiry than the narrow type of reanalysis that EPA's proposal is focused on. Validation involves evaluating all of the available science around the hypothesis being explored, not just a determination that no errors or incorrect leaps-of-faith have occurred in reaching a conclusion from a given set of data.

EPA's proposed definition for "data" also suggests that "the scientific community" perceives availability of data to be inherent to study validation. This construct, however, is entirely of EPA's making, and the agency is incorrectly attributing its flawed notions of validation to the scientific community. EPA has in fact failed to provide any analysis as to what the scientific community believes to be involved in study validation.

- Independent validation. EPA provides the following proposed regulatory definition for "independent validation":

> [T]he reanalysis of study data by subject matter experts who have not contributed to the development of the study to demonstrate that the same analytic results reported in the study are capable of being substantially reproduced.[358]

The definition of "independent validation" suffers from the same problems as described for "capable of being substantially reproduced" in that EPA is inappropriately conflating "validation" with "reanalysis." Validation of scientific data is not accomplished by simply *independently reanalyzing* the data. False or inappropriately obtained data will be *invalid* regardless of whether it can be *independently reanalyzed*. Reproducing study results using a different population or method is generally considered a stronger approach to validation, rather than simply reanalyzing the results using the same data, as it shows that the results hold across different populations and different study designs.[359] Furthermore, even accepting EPA's focus on reanalysis, the agency has not identified what information would

[357] *Data*, MERRIAM-WEBSTER DICTIONARY ONLINE (last visited May, 17, 2020), https://www.merriam-webster.com/dictionary/data.

[358] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

[359] *See, e.g.*, Comments of the International Society for Environmental Epidemiology on EPA's Proposed Rule on Strengthening Transparency in Regulatory Science, Docket ID No. EPA-HQ-OA-2018-0259-1973, at 2 ("However, although data reanalysis has a role to play, ultimately, the key determination of the consistency of scientific evidence comes from replication, not reanalysis."). Note that ISEE uses the term "replicate" to mean what we have defined in these comments as "reproduce."

be needed for independent validation of different areas of research. For example, the Final SAB Report raises additional points regarding the deficiencies in EPA's proposed definition for independent validation, highlighting the significant ambiguity that remains and insufficient attention to other, related considerations:

> EPA's supplemental proposal indicates that independent validation means the reanalysis of study data by subject matter experts who have not contributed to the development of the study to demonstrate that the same analytic results reported in the study are capable of being substantially reproduced. However, the specific definition of independent validation drives the feasibility of whether EPA can make data and models available for independent validation. For example, the EPA should consider the following questions: How much information is sufficient for independent validation? Will this information consist of equations where reviewers can verify the math, more detailed models where assumptions and limitations are described, or code to allow the public to evaluate and run the models if desired? Is this information simply the dose-response data for the endpoint of concern driving a regulatory limit, or is it availability of all data from a pivotal study to allow reviewers to examine the potential contributions of other variables on the primary endpoint of concern? Endpoint data are seldom evaluated in isolation so providing sufficient study information to allow an independent assessment seems important to meet the goals of the Proposed Rule. For example, an effect on pup body weights in a toxicology study should be examined with knowledge of maternal gestational body weight gains, litter size, food consumption, maternal/litter clinical signs, etc. Sample size and variability also play a key role in data interpretation.[360]

- Pivotal science. EPA proposes to define "pivotal science" as "the specific scientific studies or analyses that underly [sic] influential scientific information."[361] This definition is grossly ambiguous and wholly inadequate. It fails to provide any specificity as to what would qualify as a study that *underlies* influential scientific information. Many studies are included in the development of influential scientific information, whether as supporting evidence in a weight of evidence approach or more directly to derive values related to exposure, hazard, or risk or other forms of conclusions. As defined, "pivotal science" could include all studies involved in the development of influential scientific information, both supportive studies and studies used to derive specific values or other final conclusions. Application to all such studies would be entirely infeasible, effectively paralyzing the development of influential scientific information and with it the work of the agency. Conversely, to the extent the agency intends to apply the proposal to some narrower set of

[360] Final SAB Report at 12.

[361] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

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studies, the definition is entirely deficient and introduces incredible risk for selective and biased application with no accountability.

- Publicly available. The proposal provides the following definition for "publicly available":

> [L]awfully available to the general public from federal, state, or local government records; the internet; widely distributed media; or disclosures to the general public that are required to be made by federal, state, or local law.[362]

In general scientific usage, "publicly available" means the data, methods, results and summary evaluation are available in a usual form (e.g., a peer-reviewed scientific publication or a technical report). The definition proposed by EPA goes well beyond the generally accepted scientific definition and is likely to mislead the public into believing that the agency's definition is the scientific norm.

VII. EPA'S FAILURE TO ANALYZE THE COSTS AND BENEFITS OF THE SUPPLEMENTAL NOTICE IS ARBITRARY AND UNLAWFUL

A. THE SUPPLEMENTAL NOTICE EXACERBATES EPA'S ARBITRARY FAILURE TO ASSESS COSTS AND BENEFITS DESPITE COMMENTS FILED POINTING OUT THIS FATAL DEFICIENCY OF THE 2018 PROPOSAL.

The Supplemental Notice would effect a major change in how EPA establishes public health protections without any consideration of the impacts or burdens that the policy would inflict upon the agency, the research community, vulnerable populations, or the public at large. In comments on the 2018 proposal, EDF and others demonstrated that EPA failed to provide any assessment of the costs and benefits—either quantitatively or qualitatively—and thus fell gravely short of basic requirements for reasoned decision-making.[363] Far from correcting that fatal shortcoming, the Supplemental Notice exacerbates the problem by conjuring an even more expansive policy from the same deficient record. Indeed, the word "cost" appears nowhere in the Supplemental Notice, except in titles of two documents cited for other purposes.

It is arbitrary and capricious to "'entirely fai[l] to consider an important aspect of the problem' when deciding whether regulation is appropriate."[364] As in *Michigan*, EPA's present failure to consider the costs and benefits of a regulation where there is no statutory bar to doing so

[362] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

[363] EDF 2018 Comments at 101-108.

[364] *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (quoting *State Farm*, 463 U.S. at 43).

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is arbitrary and capricious.[365] Moreover, EPA's failure to characterize costs and benefits necessarily precludes the agency from assessing whether the costs are disproportionate to the benefits, a finding that could render the proposal arbitrary and capricious.[366] As described below, this failure extends to harms that the proposal would inflict upon the public at large, vulnerable populations, the research community, and the agency.[367] EPA does not identify any statutory authority that could justify its failure to assess the costs and benefits of the proposed rule, and it is certain that the agency could not rely on a radical use of a generally applicable statute like the Housekeeping Act in order to evade well-established requirements of administrative law.

In addition to defying Supreme Court precedent, EPA has contravened Executive Order 12,866 as well as its own guidance on how to implement that Executive Order. For significant regulatory actions like the instant proposal, agencies are required to prepare "[a]n assessment, including the underlying analysis," of both the costs and the benefits.[368] The Executive Order expressly contemplates a wide range of costs, including costs "to the government in administering the regulation" and "any adverse effects on health, safety, and the natural environment."[369] These requirements are especially important in the context of this proposal, which is not only a significant regulatory action in its own right, but also explicitly applies to future "final regulations determined to be 'significant regulatory actions' under E.O. 12866."[370] It is indefensible for the agency not to analyze the costs and benefits of a significant regulatory action that is in turn intended to affect an untold number of additional significant regulatory actions in perpetuity. EPA's failure to do so is arbitrary, capricious, and unlawful.

It is no defense that EPA characterizes this rulemaking (wrongly) as pertaining to internal organization or procedure. The costs to the public are significant and foreseeable. As this policy would likely result in weaker protections from pollutants, toxicants, and other threats, costs would manifest in the form of illness, premature death, medical expenses, missed school and work days, and more. Additionally, as discussed below, the rule would inflict costs upon the research community whose work has long formed the foundation for EPA's public health protections. Even

[365] *See id.* ("Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions.").

[366] *See id.* at 2710.

[367] *See id.* at 2707 ("'[C]ost' includes more than the expense of complying with regulations; any disadvantage could be termed a cost.").

[368] E.O. 12,866 § 6(a)(3)(C); EPA, Office of Policy, *EPA's Action Development Process: Guidance for EPA Staff on Developing Quality Actions* at 49 (2011) (EPA proposed rules covered by EO 12,866 are to contain the OMB Circular A-4 economics table and a regulatory impact analysis).

[369] E.O. 12,866 § 6(a)(3)(C)(ii).

[370] 83 Fed. Reg. at 18,771, 18,773.

if there is uncertainty about how costs would materialize, EPA must make a reasonable effort to estimate them. EPA cannot assume the costs to be zero—or ignore the issue altogether.[371]

Here, any inability of EPA to assess costs is largely attributable to the deficiencies in the agency's rulemaking process. As noted elsewhere in these comments, EPA has failed to articulate a defensible rationale for this proposal or to describe what effects the proposal might produce. The SAB recently observed that "[c]osts of processing and documenting data will be difficult to assess in advance until EPA has developed a system for dealing with the requirements of the rule."[372] Basic ambiguities in the proposal might further obscure potential costs, as the SAB noted with respect to the definition of "data."[373]A reasoned decision-making process would have generated more information upon which to analyze costs and benefits, rather than the near-total absence of information that we now face. This lack of information is not carte blanche to forego an analysis, but rather an indication that this rulemaking is arbitrary and unsupported.

That EPA might analyze costs and benefits of future rulemakings that implement this policy is no substitute for analyzing costs now.[374] Moreover, in future rulemakings, the methodology of this policy would already be baked into the process, and disentangling its specific impacts would be virtually impossible. To do so, EPA would have to identify which studies it would have relied on (or weighted differently) but for this rule, the difference in the standards or other outcome that would have resulted, and the costs and benefits the counterfactual standards would have yielded. And even then, this rule would have been long since finalized, so any assessment of costs and benefits would come far too late to influence EPA's decision-making. Moreover, analyzing the costs of this rule only as-applied in future rulemakings would be unlikely to capture costs imposed on the research community or resulting from the public's reluctance to participate in studies as a result of this policy.[375] As described above,[376] the influential scientific information to which this proposal would apply may be utilized in processes other than EPA rulemakings—such as to inform decisions by state and local health agencies—that would not provide even a theoretical opportunity for EPA to assess the costs and benefits of this proposal.

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[371] *See State Farm*, 463 U.S. at 43; *see also Ctr. for Biological Diversity v. NHTSA*, 538 F.3d 1172, 1200 (9th Cir. 2008) (agency acted arbitrarily and capriciously when assigning zero value to benefits which were real but difficult to quantify; failure to account for such benefits is tantamount to assigning zero value).

[372] Final SAB Report at 14.

[373] *Id.* at 17.

[374] *See Michigan v. EPA*, 135 S.Ct. at 2709 ("Cost may become relevant again at a later stage of the regulatory process, but that possibility does not establish its irrelevance at this stage.").

[375] *See id.* at 2710 (noting lack of assurance "that the consideration of cost at subsequent stages will ensure that the costs are not disproportionate to the benefits").

[376] *See* Section III.A, *supra*.

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EPA's failure to characterize and consider costs and benefits is especially arbitrary and unlawful in the context of a proposal that ostensibly strengthens regulatory transparency. EPA's 2018 proposal asserted: "By better informing the public, the Agency i[s] enhancing the public's ability to understand and meaningfully participate in the regulatory process."[377] Ironically, in the rulemaking at hand, EPA deprives the public of information that is essential to meaningful participation and accountability. Equally concerning, EPA appears not to have developed that information even for its internal consideration. In the following sections, we describe some of the cost considerations that EPA arbitrarily and unlawfully failed to assess.

B. EPA Fails to Consider Costs to the Research Community Potentially Associated with Making Data Available for Reanalysis.

The costs that this proposal would impose on the research community would likely be significant and pervasive, thoroughly impacting the scientific process. These costs are even higher than those that would have been imposed under the 2018 proposal because of the wider range of studies and EPA actions encompassed by the Supplemental Notice. EPA's failure to consider these costs is arbitrary and unlawful.

EPA cannot disregard these costs by claiming that the Supplemental Notice does not directly impose requirements upon the research community. Researchers performing public health and environmental studies have an ethical, professional, and personal stake in how their studies are utilized. It is untenable for EPA to ignore the impacts that this proposal would have on the research community, as if scientists would—or even could—conduct their research in a vacuum, with complete indifference to whether their work would be deemed unsuitable for consideration by the nation's top environmental regulator.

For researchers who attempt to satisfy the parameters of this rulemaking by restructuring their studies to disclose underlying data, the process would be costly and convoluted. The recent SAB report notes several contexts in which costs for researchers could increase, including "researchers' time to collate data and work with EPA to make these data publicly available," and likely "additional costs that occur at an institutional level (i.e., Institutional Review Boards) that would be substantial."[378] Furthermore, "there are legitimate legal, ethical, professional and financial reasons why researchers may be unable or unwilling to fully share 'data.'"[379] As noted in Section I.D of these comments and further below, individual members of the SAB have also observed that study subjects may decline to participate in studies if researchers may ultimately

[377] 83 Fed. Reg. at 18,769.

[378] Final SAB Report at 15.

[379] *Id.* at 17.

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share their data with others, raising serious concerns that researchers who attempt to comply with the requirements of this proposal will have difficulty persuading members of the public to participate in studies, or that participation in such studies may be biased or skewed in ways that would influence the results. As described above, this proposal lacks any discernible benefit, so researchers' efforts to meet EPA's arbitrary strictures would be superfluous to any measures taken to ensure scientific rigor and valid, evidence-based outcomes. Such efforts would increase costs and administrative burdens but provide almost nothing in return except checking off EPA's irrational requirements.

Researchers unable to obtain additional funding would have two options. First, they could continue their study without meeting EPA's requirements (assuming funders would support a study that the agency would ignore), with the bleak awareness that its benefit for public health and the environment—not to mention the researchers' professional advancement—might be arbitrarily thwarted by EPA. Second, they might drop the study entirely in order to avoid the agency's erratic minefield of requirements, which would deprive the entire public of the benefits of their study.

Even if some researchers obtained additional funding in order to meet the proposal's requirements, studies by other researchers may be imperiled. As scientific research becomes more expensive in order to meet the proposal's parameters, there is little reason to expect that the total pool of research funding would increase commensurately. If the cost of each study increases, and the total funding remains constant, then fewer studies could be funded. This financial strain could impede not only studies incompatible with the proposal's arbitrary criteria, but even those that are compatible, drastically winnowing the available body of evidence upon which to base public health protections. As a member of the SAB has noted, organizations that devote resources to meet the proposal's requirements "will have to shift funding from ongoing, vital new research to fund this activity, at the net negative cost to the nation's health."[380] Aside from constraining funds available for new research, the proposal would pose unique challenges when applied retrospectively to prior research, possibly precluding the use of past studies, with distortionary impacts on agency analyses.[381]

It bears noting that not all funders would be equally disinclined to support research meeting EPA's requirements. For instance, research backed by industry that profits from pollutants or toxicants might be adequately resourced to adapt to EPA's new requirements, since such funders would have a financial interest in which studies the agency considers. The proposal could thereby

[380] SAB Consultation at B-25 (comments of Robert W. Merritt).

[381] "[R]etrospective application of the requirement . . . could arbitrarily impact the conclusions drawn." Final SAB Report at 17.

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skew the research landscape in favor of studies whose funders hope to reap a monetary benefit from the outcome of the research.[382]

The introduction of the tiered access alternative in the Supplemental Notice raises major additional concerns about the costs to the research community. As explained elsewhere in these comments,[383] the tiered access approach would likely be difficult and costly to administer, but EPA has not explained, even in general terms, how this approach would be implemented, the degree of burden it would impose, or who would bear the costs. However, in a recent briefing with staff on the House Committee on Science, Space, and Technology, EPA staff revealed that "key implementation responsibilities [for tiered access] will fall on the research community."[384] EPA's apparent expectation that it will impose massive new costs on the research community without acknowledging as much in the Supplemental Notice is arbitrary and a violation of notice requirements. It would further privilege EPA's reliance on studies from wealthy organizations or those with a financial incentive to expend the necessary resources for EPA to consider their work.

C. EPA Fails to Consider Costs to the Public Resulting from Weaker Health and Environmental Protections.

As EDF explained in its comments on the 2018 proposal, the most important costs of this rule would be associated with public health and environmental regulations that do not reflect the best available science.[385] EPA's failure to consider these costs is arbitrary and unlawful. The proposal would likely result in EPA's exclusion or subordination of research that indicates a link between pollutants and toxicants on the one hand, and human death and morbidity on the other. EPA's regulations would likely be insufficiently protective of public health and the environment due to the exclusion of research demonstrating the harm caused by various substances and activities. In particular, EPA is subject to requirements, ranging from statutes to executive orders, to consider the impacts of its regulations on vulnerable populations.[386] EPA has not addressed how the implementation of this proposal would intersect with those requirements. The proposal would provide EPA with a means to paper over human suffering but weaken the agency's ability to prevent it.

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[382] *See* SAB Consultation at B-25 (comments of Robert W. Merritt) (raising the possibility that "only organizations producing results favorable to deep-pocketed industrial concerns will easily find funding to participate").

[383] *See* Section V.B, *supra*.

[384] Memo to Chairwoman Johnson, *supra* note 120, at 3.

[385] EDF 2018 Comments at 103.

[386] *See, e.g.*, 42 U.S.C. § 7409(b)(1) (requiring EPA to set national ambient air quality standards with "an adequate margin of safety . . . to protect the public health"); Exec. Order 13,045, "Protection of Children from Environmental Health Risks and Safety Risks," 62 Fed. Reg. 19,885 (Apr. 23, 1997); Exec. Order 12,898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-income Populations," 59 Fed. Reg. 7629 (Feb. 16, 1994).

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Moreover, as noted above, this proposal could prevent many studies from being performed at all, at a significant cost to society. Many state and local environmental regulators could be expected to continue utilizing the best available science rather than adopt EPA's meritless criteria. In addition, individuals could still use studies spurned by EPA to protect themselves from harm. But by imposing scientifically baseless financial barriers and other disincentives to pursuing these studies, EPA would deprive all stakeholders of the studies' benefits. And as explained above, the proposal could raise the costs and decrease the quantity of even those studies that would meet EPA's requirements, further depriving EPA of a robust scientific record when establishing public health and environmental protections.

D. EPA Fails to Consider the Costs of Discouraging Public Participation in Research Studies.

Another way that EPA's arbitrary fixation on the public availability of underlying data would impair scientific research is the deterrent effect on study participants. As EDF explained in comments on the 2018 proposal, confidentiality pledges to study participants are often essential in order to collect accurate and complete information.[387] This concept was reinforced by an SAB member, who advised EPA that the possibility of disclosure of personally identifiable information would "[c]ertainly . . . cause[] some participants to decline participation."[388] The proposal could encumber the researcher-participant relationship by introducing several unnecessary concerns into the process. First, some subjects in public health studies may lose confidence that their data will remain confidential. Even if researchers withhold the names of study participants, the increased pressure on researchers to release information could instill a reasonable fear in subjects that their data could be traced back to them. Second, if researchers committed to keeping underlying data confidential, subjects might reasonably fear that EPA would arbitrarily disregard the findings of the study, lowering their incentive to participate. In some contexts, EPA seems to acknowledge that study participants are motivated in part by the potential impact of a study on public health protections.[389] And third, by imposing new requirements for data availability that have no scientific basis, EPA may create a false impression that the public release of data is an indicator of study

[387] EDF 2018 Comments at 105.

[388] SAB Consultation at B-10 (comments of Janice Chambers).

[389] *See* EPA, *Clinical Studies in Environmental Health, Questions & Answers*, https://epastudies.org/public/epastudies/QuestionsAndAnswers.aspx#q10 (last updated Mar. 20, 2020) ("Thanks to people like you who have participated in studies at the Human Studies Facility, the EPA has set air pollutant regulations that help improve the health of millions of individuals every year. Your participation will help make the world a better and healthier place for us all."); EPA, *Clinical Studies in Environmental Health, Study Results*, https://epastudies.org/Public/EPAStudies/Results.aspx (date of last update not indicated) ("Results of studies performed by the Human Studies Facility . . . directly impact the creation of regulations responsible for protecting the health and environment of millions of Americans.").

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quality. This could deter participants from participating in studies for which data will be kept confidential.

As a result, scientific research would become more arduous and expensive. Fewer studies could be performed, to the detriment of public health policy at EPA and other regulatory bodies. EPA's failure to consider these costs is arbitrary and unlawful. While these concerns also applied to the 2018 proposal, the expanded scope of the Supplemental Notice greatly exacerbates them.

E. EPA FAILS TO CONSIDER COSTS THE AGENCY WOULD INCUR IN REVIEWING STUDIES.

Expanding upon a defect in the 2018 proposal, EPA has failed to estimate the costs the agency would incur to implement the proposal, despite the availability of information upon which to base such estimates. Executive Order 12,866 specifically includes costs "to the government" among the costs the agency "shall consider."[390] It again references costs "to the government" when describing the required assessments for significant regulatory actions.[391] Moreover, the costs of administering a regulation are plainly relevant to the reasonableness of an agency's interpretation of the statutes supposedly authorizing the regulation.[392]

The Congressional Budget Office (CBO) has repeatedly estimated the cost of the failed congressional bills that inspired this proposal, generating estimates exceeding $100 million per year—assuming that EPA takes the necessary steps to bring all the studies it relies upon into compliance with the policy.[393] Alternatively, CBO estimated that EPA might reduce those costs to $5 million over a five-year period, but only by "significantly reduc[ing] the number of studies that the agency relies on."[394] EPA failed to address these costs—including the effects of potentially relying on fewer studies—in the 2018 proposal, and it has failed to do so again in the Supplemental Notice, even though commenters provided these figures in their 2018 comments. EPA's present failure to address the CBO estimates is even more arbitrary than in 2018—and not only because the estimates are now clearly in the record. In addition, the Supplemental Notice more closely

[390] E.O. 12,866 § 1(b)(5).

[391] *Id.* § 6(a)(3)(C)(ii).

[392] *See Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 322-24 (2014).

[393] *See, e.g.*, CBO Estimate for H.R. 1430, *supra* note 271; *see also* CBO Estimate for S. 544, *supra* note 4, at 3 (estimating that another, similar bill would cost up to $250 million per year, even if EPA halved the number of studies it relied upon); Ben Levitan, *Public Records Confirm EPA's "Censored Science" Proposal Was an End-Run Around Congress*, EDF Climate 411 Blog (Nov. 12, 2019) (describing public records showing that the proposal was expressly intended to implement the HONEST Act), http://blogs.edf.org/climate411/2019/11/12/public-records-confirm-epas-censored-science-proposal-was-an-end-run-around-congress/.

[394] CBO Estimate for H.R. 1430, *supra* note 271, at 1-2.

parallels the bills that CBO reviewed due to the expanded scope of agency actions and studies it would encompass.

EPA now disclaims any responsibility to make data and models available for independent validation so that the agency could use them in its regulatory decisions and influential scientific information.[395] Yet significant—and entirely unassessed—administrative costs remain, including those associated with identifying pivotal regulatory science and pivotal science, determining whether underlying data and models are available in a manner sufficient for independent validation, and deciding whether to exempt any of the numerous studies that would otherwise be off-limits. The SAB has recently and repeatedly raised concerns about the complexity of these self-imposed tasks.[396] EPA cannot finalize any rule resembling the proposal until it conducts a thorough accounting of these and other costs to the agency, which could prove impossible given the incoherent nature of its requirements.

F. EPA Fails to Quantify, Characterize, Analyze, or Disclose the Benefits of Its Proposal.

The Supplemental Notice does not cure EPA's failure in the 2018 proposal to articulate the benefits of its policy. The error is even more glaring now that the scope of the proposal has significantly expanded. If the 2018 proposal had any merit, it would have contained at least the seed of benefits that should be all the more obvious now that the proposal covers a wider range of studies and actions. Yet EPA still has not characterized what positive outcomes this proposal would deliver. EPA's failure to characterize or analyze the benefits of its proposal—or to acknowledge the absence of benefits—is arbitrary and unlawful.

VIII. CHANGES TO THE PROPOSED RULE'S EXEMPTION PROVISIONS

A. The Changes to the Proposed Rule's Exemption Provisions Do Nothing to Remedy the Fundamental Unlawfulness of the Proposed Rule.

As explained in EDF's 2018 comments, the originally proposed exemption provisions did nothing to remedy the fundamental unlawfulness of prohibiting EPA from considering valid and

[395] 85 Fed. Reg. at 15,402.

[396] *See* Final SAB Report at 8 ("[I]dentification of all studies and regulatory science supporting regulatory actions . . . will be a complex process."); *id.* at 9 ("It may also be very challenging to identify pivotal studies if holistic judgments and weight-of-evidence frameworks are used."); *id.* at 12 (discussing the difficulty of determining whether data and models are sufficiently available for independent validation); *id.* at 16 (noting that "it may be difficult to develop criteria for exceptions" and that "EPA cannot address all circumstances and scenarios that could limit data sharing").

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relevant studies due to the public unavailability of underlying data and methods.[397] The changes to the exemption provisions announced in the Supplemental Notice do nothing to warrant altering that analysis.

Specifically, numerous environmental and public health statutes *require* EPA to consider all available science and other relevant information when making regulatory decisions,[398] but if a study fails to meet the proposed rule's public disclosure requirements, the Supplemental Notice's exemption provisions, like the originally proposed provisions, would merely *allow* the Administrator to exempt a qualifying study. Thus, the proposed exemption provisions would give the Administrator unfettered discretion to ignore a study that fails to satisfy the proposed rule's public availability requirements, even if that study constitutes the best available science (and perhaps, is the *only* available science). Furthermore, there may be circumstances where a study does not meet the rule's disclosure requirements *and* does not qualify for an exemption, but nonetheless constitutes the best available science. Under such circumstances, the Administrator could not consider the study even in the face of his or her statutory obligation to do so.

As EDF explained in its 2018 comments, there are many reasons that underlying study data and models may not be available that have no bearing on the quality or validity of the study, including legal restrictions or concerns about privacy.[399] Indeed, EPA's proposal to allow the Administrator to grant exemptions from the rule's disclosure requirements demonstrates EPA's awareness that a study can be valid and worthy of consideration even if underlying data or models are not publicly available. Where a statute requires that the agency consider certain information in reaching a decision, EPA cannot promulgate a rule that prohibits the Agency from considering such information, that automatically downgrades the value placed on such information regardless of its scientific merit, or that gives the Administrator discretion to decide whether the Agency will consider such information. None of the Supplemental Notice's changes to proposed section 30.9 do anything to resolve this fundamental conflict with the relevant environmental and public health statutes. The mere fact that the Administrator might in the future use his or her exemption authority to allow the agency to consider a particular study does not resolve the rule's unlawfulness.[400]

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[397] EDF 2018 Comments at 32-33.

[398] *Id.* at 14-32.

[399] *Id.* at 36-40; *see also* Final SAB Report at 17 ("[T]here are legitimate legal, ethical, professional and financial reasons why researchers may be unable or unwilling to fully share 'data' - including statutes protecting participant privacy, experimental protocols assuring confidentiality of data for human subjects, and (for past studies) issues related to degradation and custody of data."). In fact, under the Supplemental Notice, the Administrator need not exempt a study from the requirement to make data and models publicly available even under circumstances where such disclosure "would conflict with laws governing privacy, confidentiality, confidential business information, or national and homeland security." 85 Fed. Reg. 15,406.

[400] *Cf. Sierra Club v. EPA*, 536 F.3d 673, 678 (D.C. Cir. 2008) (where the Clean Air Act required source-specific operating permits to include monitoring sufficient to assure compliance with applicable requirements, the court held

B. EVEN IF THE ADMINISTRATOR HAD LEGAL AUTHORITY TO IGNORE A VALID SCIENTIFIC STUDY BASED SOLELY ON THE PUBLIC UNAVAILABILITY OF MODELS AND DATA, THE EXEMPTION PROVISIONS ARE ARBITRARY BECAUSE THEY ARE BOTH TOO VAGUE AND TOO LIMITED.

The proposed exemption provisions are also arbitrary in that they are both too vague and too restricted to ensure that the Administrator considers the most valuable and reliable studies when formulating environmental rules and policies.

As explained in EDF's 2018 comments, the exemption provisions are too vague because they fail to define sufficient criteria or process steps by which the Administrator shall apply the exemption criteria.[401] While the Supplemental Notice clarifies that the exemption for circumstances where it is "infeasible" to make models and studies available pertains only to "technological barriers,"[402] it remains unclear whether this determination could be based on cost or other practical concerns, or whether the exemption would be available only where the necessary technology does not exist. Likewise, while the Supplemental Notice would authorize the Administrator to exempt a study for which the development of the data or model was completed or updated before the effective date of the final rule, it offers no criteria to govern when granting an exemption based on the study's age is appropriate. Thus, the Administrator would possess nearly absolute discretion in deciding whether to grant an exemption from the rule's requirements. In fact, like the originally proposed exemption provisions, the Supplemental Notice's exemption provisions lack any specific requirement for the Administrator to provide a public, written explanation of his or her decision to grant (or deny) an exemption. Thus, there would be no way to hold the Administrator accountable for arbitrarily applying the exemption provisions to consider those studies that are favorable to the current Administration's position while excluding those that are unfavorable but of equal or greater scientific validity. While EPA apparently initially intended to include specific criteria for determining whether application of the exemption provision is warranted with respect to a particular study, OMB directed EPA to remove that criteria for unknown reasons.[403]As the SAB Report on this proposed rulemaking notes, the absence of specific criteria to guide the Administrator's application of the case-by-case exemption provisions "may create concerns about inappropriate exclusion of scientifically important studies."[404] Likewise, the

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that EPA's "vague promises to act in the future" to correct inadequate monitoring in federal regulations was not enough to justify EPA's promulgation of a regulation prohibiting state permitting authorities from supplementing inadequate monitoring in applicable regulations when issuing an operating permit).

[401] EDF 2018 Comments at 33.

[402] 85 Fed. Reg. at 15,403.

[403] EPA, Documentation of Changes Made During EO 12866 Review, Docket ID No. EPA-HQ-OA-2018-0259-9321, at 50-51 (2020).

[404] Final SAB Report at 16.

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SAB Report explains that those waivers that the Administrator does grant "might appear to be inconsistent or lacking objectivity."[405]

The Supplemental Notice's exemption provisions are also arbitrarily limited because they fail to provide the Administrator with any general exemption authority to apply when unforeseen circumstances necessitate a deviation from the rule's disclosure provisions. While EPA solicits comment on whether there are additional circumstances where an exemption would be warranted, it is impossible to foresee every such circumstance. As the SAB Report explained, the proposed rule's exemption provisions "may not be an effective mechanism for ensuring that the EPA can appropriately consider important studies."[406] Given the importance of EPA's decisions in ensuring the protection of public health and the environment—and that nothing in this rulemaking demonstrates that a study that fails to meet the rule's model and data availability requirements cannot nonetheless constitute the "best available science"— EPA must have the flexibility to consider a study when presented with a compelling justification that it is infeasible to comply with the rule's requirements.

C. THE SUPPLEMENTAL NOTICE'S EXEMPTION PROVISIONS ARBITRARILY FAIL TO REQUIRE THE ADMINISTRATOR TO CONSIDER THE MOST CRITICAL FACTOR IN WHETHER A SCIENTIFIC STUDY SHOULD BE CONSIDERED: WHETHER THE STUDY HAS BEEN SUFFICIENTLY REVIEWED AND VALIDATED TO MAKE IT RELIABLE DESPITE THE PUBLIC UNAVAILABILITY OF UNDERLYING DATA AND MODELS.

For EPA's proposed rule to be lawful, EPA would have to be able to demonstrate that the public unavailability of underlying data and models can, by itself, be dispositive of a study's validity. As explained in EDF's 2018 comments, EPA has made no such demonstration.[407] The Supplemental Notice's exemption provisions further confirm the unlawfulness of EPA's proposal by omitting from the Administrator's exemption criteria any consideration of whether a study is valid despite the public unavailability of underlying data and models.[408]

No factor could be more central to whether EPA considers a particular scientific study in formulating a rule or policy than whether the study has been sufficiently validated to serve as a reliable foundation for agency decision-making. EPA's failure to identify that consideration as a core criterion in the Administrator's decision as to whether to grant an exemption from the

[405] *Id.*

[406] *Id.*

[407] *See* EDF 2018 Comments at 16-22.

[408] *See* 85 Fed. Reg. at 15,406 (proposed 40 C.F.R. § 30.9).

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proposed rule's public disclosure requirements renders the proposed exemption provisions arbitrary.[409]

EPA's failure to identify consideration of whether study is reliable despite the lack of public disclosure of underlying models and data as a prerequisite to a decision by the Administrator to waive the proposed rule's requirements for that study makes sense only if (a) EPA does not believe that public disclosure of underlying data and models is relevant to a study's reliability, or (b) EPA is willing to exempt a study from the rule's requirements despite the lack of mechanisms to ensure the study's reliability. Either way, the exemption provisions demonstrate the arbitrariness of the proposed rule.

D. EPA Should Eliminate the Proposed Exemption for Data and Models Completed or Updated Before the Final Rule's Effective Date and Instead Clarify that the Rule Does Not Apply Retroactively.

EPA's Supplemental Notice includes new language in proposed section 30.9 specifying that one of the bases on which the Administrator could choose to exempt a study from the rule's public availability requirements is that "the development of the data or model was completed or updated before" the effective date of the final rule.[410] EPA "requests comment on this consideration of the age of data and models in determining the feasibility of making underlying data and models publicly available."[411] As explained above, EDF opposes this regulatory language because the rule should not have any retroactive application.[412] EDF opposes the proposed rule in its entirety, but if EPA finalizes it, EPA must strike this exemption and instead confirm in section 30.5 that there will be no retroactive application of the rule.

E. If EPA Persists in Finalizing the Proposed Rule's Mandatory Peer Review Requirements, EPA Must Authorize the Administrator to Waive or Defer Peer Review Requirements When Presented with a Compelling Rationale.

In its comments on the original proposal, EDF raised numerous significant concerns regarding the proposed rule's new peer review requirements.[413] The Supplemental Notice does

[409] *See, e.g.*, *State Farm*, 463 U.S. at 43 ("Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem.").

[410] 85 Fed. Reg. at 15,406.

[411] *Id.* at 15,403.

[412] *See* Section I.E, *supra*.

[413] EDF 2018 Comments at 94-96.

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nothing whatsoever to address those concerns. To the contrary, the Supplemental Notice creates more problems by proposing to delete the originally proposed language authorizing an exemption where EPA determines that peer review is "infeasible."[414] According to EPA, this exemption is unnecessary because EPA "does not believe that peer review of pivotal regulatory science or pivotal science would be infeasible."[415]

EPA's claim that there are no circumstances under which peer review would be infeasible is inconsistent with OMB's Peer Review Bulletin.[416] Specifically, Section VIII of the Bulletin provides that an agency may defer or waive peer review requirements based on a "compelling rationale."[417] Certainly, it is possible that costs, expediency or some other unforeseen circumstance may necessitate that EPA consider a study that has not been peer reviewed. As the OMB explained when issuing the Peer Review Bulletin, this general authority to waive or defer peer review requirements "ensure[s] needed flexibility in unusual and compelling situations not otherwise covered by the exemptions in the Bulletin before information is disseminated."[418] While proposed section 30.7 continues to provide that the rule's peer review requirements must be applied in a manner that is "consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review and the Exemptions described therein,"[419] EPA's declaration that there will not be circumstances where peer review would be infeasible, combined with EPA's express decision to eliminate the peer review exemption from proposed section 30.9, could be interpreted as overriding the general waiver and deferral authority provided by Section VIII the OMB Peer Review Bulletin. Eliminating—or even casting doubt upon—the Administrator's flexibility to waive or defer peer review requirements when confronted with unforeseen circumstances and a "compelling rationale" is unwarranted and risky. If EPA moves forward with finalizing its proposed peer review requirements—which, for the reasons set forth in EDF's 2018 comments, it should not—EPA must add language to proposed section 30.9 clarifying that the Administrator possesses authority to defer or waive peer review requirements based on a compelling rationale.

[414] 85 Fed. Reg. at 15,403.

[415] *Id.* In its 2018 comments, EDF argued that the peer review exemption language was flawed in that it was more restrictive than the authority provided by OMB's Peer Review Bulletin. *See* EDF 2018 Comments at 95-96.

[416] Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664, 2677 (Jan. 14, 2005).

[417] *Id.*

[418] *Id.* at 2673.

[419] 85 Fed. Reg. at 15,406.

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IX. EPA'S SUPPLEMENTAL NOTICE VIOLATES THE PROCEDURAL REQUIREMENTS OF THE APA, CAA, AND VARIOUS OTHER STATUTES

A. EPA HAS PROVIDED INSUFFICIENT TIME FOR MEANINGFUL PUBLIC COMMENT AND UNLAWFULLY FAILED TO HOLD A PUBLIC HEARING.

The Administrative Procedure Act "requires that the public have a meaningful opportunity to submit data and written analysis regarding a proposed rulemaking."[420] The purposes of the APA's notice and comment requirements are "(1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review."[421]

The Clean Air Act likewise requires that the public be permitted to meaningfully comment on EPA's proposed rulemakings.[422]

Given the complexity of this Supplemental Notice and the immediate public harms that could result from this rule, the 61-day comment period for this Supplemental Notice clearly fails to satisfy EPA's obligation to provide a meaningful opportunity for public comment. The Supplemental Notice builds on the highly controversial 2018 proposal to sharply restrict EPA's consideration of pivotal public health science when making decisions on vital health, safety, and environmental protections issued under a broad range of federal statutes. Responding to public outcry over the inadequacy of the length of the original comment period, and recognizing the complexity, breadth, and significance of that proposal, EPA ultimately afforded a full 108 days for

[420] *Prometheus Radio Project v. FCC*, 652 F.3d 431, 453 (3d Cir. 2011) (citing 5 U.S.C. § 553(c)); *see also Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1101 (D.C. Cir. 2009) ("The opportunity for comment must be a meaningful opportunity.").

[421] *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005); *United States v. Reynolds*, 710 F.3d 498, 519–20 (3d Cir. 2013) ("[T]he essential purpose of according § 553 notice and comment opportunities is to reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies." (alteration in original) (quoting *Dia Nav. Co., Ltd. v. Pomeroy*, 34 F.3d 1255, 1265 (3d Cir. 1994)); *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1404 (9th Cir. 1995) ("The purpose of the notice and comment requirement is to provide for meaningful public participation in the rule-making process."). "[T]hese policy goals of maximum participation and full information" are "obvious[ly] importan[t]." *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1044 (D.C. Cir. 1987).

[422] 42 U.S.C. § 7607(d); *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 518-19, 550 ("[T]he additional notice requirements in § 307(d)(3) suggest that Congress intended agency notice under the Clean Air Act to be more, not less, extensive than under the APA."); *see Sierra Club v. Costle*, 657 F.2d 298, 398 (D.C. Cir. 1981) (public must be able to meaningfully comment on proposed Clean Air Act rule).

comment.[423] Not surprisingly, the 2018 proposal was the subject of intense public interest, ultimately drawing over 600,000 comments—including numerous substantial submissions by practicing scientific researchers, research universities, health and medical associations, state and local governments, industry associations, and environmental and health organizations. The 2018 proposal also drew highly unusual public criticism and statements of concern from the nation's leading scientific institutions, including an open letter by the editors of the nation's top scientific journals and a letter to the Administrator from the president of the National Academies of Science, Engineering and Medicine. And EPA's own Science Advisory Board, which was not even informed in advance of the 2018 proposal, found the proposal significant enough that it took the extraordinary step of conducting its own review.

The Supplemental Notice is every bit as consequential and complex as the original proposal, and warrants a comment period at least as long. For example, the Supplemental Notice radically expands the scope of the original proposal to encompass *all* data and models underpinning studies used by EPA, not just dose-response data and models. Similarly, the Supplemental Notice broadens the proposal to encompass the vast body of "influential scientific information" developed by the agency, raising an array of distinct, major concerns.[424] In addition, the Supplemental Notice presents two complex and vaguely-articulated approaches to implementing the proposed restrictions on science, each of which carries distinct practical impacts and cost implications. What is more, the Supplemental Notice introduces a suite of new regulatory definitions as well as novel claims of legal authority for this sweeping rule, including EPA's newfound theory that the Housekeeping Act permits it to adopt binding and substantive restrictions on science affecting EPA actions under a broad range of environmental laws. And the Supplemental Notice further clarifies that the proposal is intended to affect the handling of some of the most sensitive data used in health research, stating that "[p]ersonnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study" are "intended to be subject to this rulemaking."[425] There is every reason to believe that public interest in the Supplemental Notice will be just as strong as for the original proposal.

Although a 61-day comment period would have been inadequate even in ordinary times, EPA's truncated comment period is especially egregious given that the Supplemental Notice was published on March 18, 2020, amid a national crisis that particularly affects the public health experts whose input is essential to this rulemaking and who filed comments on the original proposal. Since President Trump declared a national emergency on March 13, 2020, over 1.5

[423] Strengthening Transparency in Regulatory Science; Extension of Comment Period and Notice of Public Hearing, 83 Fed. Reg. 24,255, 24,256 (May 25, 2018).

[424] 85 Fed. Reg. at 15,399.

[425] *Id.* at 15,401 (alteration in original).

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million Americans have been infected, over 90,000 have died, and over 30 million workers have lost their jobs. Public health and scientific experts are courageously attempting to prevent the pandemic from claiming more American lives. Amidst these trying and uncertain circumstances, EPA initially provided a mere 30 days for public comment, which it only extended after EDF and other stakeholders (including twenty state and city attorneys general) immediately requested that EPA suspend or substantially enlarge the comment period and hold a legally-required public hearing opportunity.[426]

EPA has declined to grant these requests without providing any persuasive justification. Importantly, EPA has identified no concrete health, environmental, or other public benefit that would require urgent action on this proposal. To the contrary, EDF and other commenters have documented extensive harms to health and environmental protections that would result from this latest attack on science. And EPA has given no other reason for why, having taken no action on its original proposal for nearly two years, public health experts, the scientific community, and the broader public should—or even could—now abruptly divert their attention from our national crisis in order to meet the agency's ill-timed and arbitrary deadline. At the same time, EPA has initiated a public comment period on its proposal to retain inadequate levels of protection from particulate matter nationwide, a process that requires full engagement from these stakeholders and only adds to the burden the agency is placing on them during the crisis.[427]

By contrast, the agency appears to believe that the national public health emergency justifies non-compliance with regulations to protect human health and welfare. A memorandum from EPA's head of enforcement, Susan Bodine, explains that the agency is "cognizant of potential worker shortages due to the COVID-19 pandemic as well as the travel and social distancing restrictions imposed by both governments and corporations or recommended by the Centers for Disease Control and Prevention to limit the spread of COVID-19," and on that basis will allow significant non-compliance with the agency's regulations.[428] Apparently, EPA believes that while the national emergency affects polluters' ability to limit pollution, it does not affect the ability of the public health organizations, doctors, and scientists who are on the front lines of responding to the national pandemic to comment on EPA's controversial Supplemental Notice.

EPA's bare 61-day comment period—on a highly complex proposal that poses grave harms to health and the environment, released in the midst of a public health emergency that has grown more dire throughout the comment period—undermines the fundamental purposes of notice and comment. EPA's Supplemental Notice will not be "tested via exposure to diverse public

[426] *See* EDF, *Request to Immediately Halt and Withdraw EPA's Censored Science Rulemaking Action*, *supra* note 6.

[427] *See* 85 Fed. Reg. 24,094, 24,094 (Apr. 30, 2020).

[428] Memorandum from Susan Parker Bodine to All Governmental and Private Sector Partners, Re: COVID-19 Implications for EPA's Enforcement and Compliance Assurance Program, at 1-2 (Mar. 26, 2020).

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comment," does not "ensure fairness to affected parties," and does not "give affected parties an opportunity to develop evidence in the record to support their objections to the rule."[429] Before finalizing any rule, EPA must extend the comment period to allow sufficient time for the entire public—including public health officials, doctors, and scientists—to comment on this dangerous Supplemental Notice.

Finally, we reiterate that section 307(d) of the Clean Air Act requires EPA to hold a public hearing on this Supplemental Notice, and to hold the record open for at least 30 days after the hearing.[430] Because the Supplemental Notice—like the original proposal—would "pertain[] to" many EPA rulemakings enumerated in section 307(d)(1), this proposal is clearly subject to the procedural requirements of section 307(d).[431] That EPA relied on the Clean Air Act as a source of authority for the original proposal, and indicates in the Supplemental Notice that it is still considering that possibility, only reinforces EPA's obligation to comply with the public hearing requirements of section 307(d).[432] EPA's failure to do so thus far is unlawful, and wrongly denies the public an important and legally-required opportunity to weigh in on this sweeping and harmful proposal.

B. EPA Continues to Violate FIFRA, Which Requires the Agency to Consult with the Department of Agriculture.

As with the original proposal,[433] the Supplemental Notice fails to comply with the pre-proposal review requirements set forth in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA continues to cite section 25 of FIFRA as a source of authority for this proposed action.[434] Section 25, however, requires the agency to seek comments from the Secretary of Agriculture on all draft proposed regulations 60 days prior to signing a proposed rule.[435] EPA is to publish this solicitation in the Federal Register,[436] and respond to any written comments from the Secretary as part of the Federal Register proposal.[437] FIFRA also requires that *any time* the EPA is required to consult with the Secretary of Agriculture, the agency must also submit a copy of the proposed rule for comment to the Agriculture Committees in the House and Senate at least 60 days

[429] *Int'l Union, United Mine Workers of Am.*, 407 F.3d at 1259.

[430] 42 U.S.C. § 7607(d)(5).

[431] *See, e.g., id.* § 7607(d)(1)(E), (R).

[432] *See* 85 Fed. Reg. at 15,397.

[433] *See* EDF 2018 Comments at 133-34.

[434] 85 Fed. Reg. at 15,397; 83 Fed. Reg. at 18,769.

[435] 7 U.S.C. § 136w(a)(2)(A).

[436] *Id.* § 136w(a)(2)(D).

[437] *Id.* § 136w(a)(2)(A).

prior to publication,[438] and provide the Scientific Advisory Panel with an opportunity to provide comment on the health and environmental impacts of the proposed action.[439]

There is no indication that EPA has satisfied any of these statutory obligations. Pre-proposal review by the Secretary, however, would at least have raised the question of what potential impacts the proposal might have on FIFRA programs—an issue on which the Supplemental Notice is mute. Congress, by requiring these consultation steps, evidently viewed them as necessary and important. EPA's disregard of these requirements is thus consequential, arbitrary, and unlawful.

C. EPA Was Required to Consult Its Scientific Advisory Committees Before Issuing the Supplemental Notice.

As with the original proposal,[440] EPA failed to submit the Supplemental Notice to the Scientific Advisory Board. This failure is particularly troubling given that the SAB requested review of the original proposal,[441] noting that "the precise design of the rule appears to have been developed without a public process for soliciting input from the scientific community."[442]

The failure to timely consult with the SAB is contrary to statute. EPA must submit its Proposal to the SAB pursuant to the requirements of the Environmental Research, Development, and Demonstration Authorization Act ("ERDDAA").[443] ERDDAA requires the Administrator to submit to the SAB any "proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the [EPA] on which the proposed action is based" at the time it provides that proposal to another agency of the government for formal review.[444]

Not only does EPA's repeated disregard of ERDDAA requirements evince troubling contempt for congressionally mandated procedures; it is also consequential. Although the Final SAB Report mentions the Supplemental Notice, it does so only fleetingly. Moreover, there was no

[438] *Id.* § 136w(a)(3).

[439] *Id.* § 136w(d)(1).

[440] *See* EDF 2018 Comments at 132-33.

[441] Memorandum from Alison Cullen, Chair of the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, to Members of the Chartered SAB and SAB Liaisons, at 2 (May 12, 2018) https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf ("This action merits further review by the SAB.").

[442] *Id.* at 3.

[443] 42 U.S.C. § 4365.

[444] *Id.* § 4365(c)(1).

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opportunity for actual SAB discussion of the Supplemental Notice, and there was consequently no public input into the SAB process, since there was no process—be it a public meeting or any other type of face-to-face deliberation of the SAB. The SAB pre-proposal review requirement in fact exists to forestall proposals as deficient as the Supplemental Notice. EPA's arbitrary failure to adhere to its legal obligation under ERDDAA renders the Supplemental Notice unlawful.

It was also arbitrary under the CAA not to consult with the Clean Air Scientific Advisory Committee (CASAC). CASAC is charged with reviewing national ambient air quality standards (NAAQS) and recommending any new standards.[445] In turn, the NAAQS are to be based on criteria that "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare."[446] CASAC's task of reviewing the NAAQS would be complicated and perhaps rendered impossible by the Supplemental Notice. CASAC could be required to recommend a change to the NAAQS based on their evaluation of valid research that EPA now seems to find objectionable,[447] which suggests that this enterprise is not what Congress intended. Further, because the Supplemental Notice would apply to influential scientific information, such as integrated science assessments prepared by agency staff,[448] EPA might itself deprive CASAC of the information it needs to fulfill its statutory duty. EPA should have considered these complexities in its rulemaking and consulted with CASAC on its implications for CASAC's duties. For these reasons as well, finalizing the proposed rule would be arbitrary and unlawful under the CAA.

[445] 42 U.S.C. § 7409(d)(2)(B).

[446] *Id.* §§ 7408(a)(2), 7409(b).

[447] See EDF 2018 Comments at 22-25.

[448] *See* Section IV.A.2, *supra*.

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Exhibit E

May 18, 2020

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Subject: Comments on Supplemental Notice of Proposed Rulemaking to the Rule "Strengthening Transparency in Regulatory Science," Docket ID No. EPA-HQ-OA-2018-0259

Dear Administrator Wheeler:

As leading scientific, engineering, and higher education organizations – which together represent hundreds of thousands of scientists, engineers, and educators – we are writing to submit our comments on EPA's Supplemental Notice of Proposed Rulemaking ("supplemental") to the Strengthening Transparency in Regulatory Science Proposed Rulemaking that was originally published on April 30, 2018.

As the scientific community has stated throughout consideration of this proposal, both when it appeared in legislation and now as a proposed rule, transparency is an essential ingredient of science and the scientific process. Scientists welcome transparency and encourage scrutiny of their work. However, this rule and supplemental are not about strengthening science, but about undermining the ability of the EPA to use the best available science in setting policies and regulations.

While the supplemental attempts to clarify the original proposed rule and address concerns previously raised by the scientific community, the changes proposed by EPA add yet another set of issues and concerns that will negatively impact the use of science at EPA and do not resolve many of our original concerns. We strongly believe the proposed rule and supplemental would diminish the critical role of scientific evidence in decisions that impact the health of Americans. Simply put, excluding the best available science, as this proposed rule would do, puts public health and the environment at risk. We strongly request the EPA rescind this proposal in its entirety for reasons outlined below.

The preeminent concern with the original rule was that by mandating all raw data be publicly available before a study can be utilized, the EPA would cut off foundational research that could best inform the agency. The supplemental offers two approaches to dealing with data that cannot or should not be made public. However, both approaches still maintain our concerns of the original rule and create more of their own.

The first proposed approach in the supplemental is a tiered access model. If a study that cannot be made public because it contains proprietary data, confidential business or personally identifiable information that cannot be deidentified, it could be considered for use by EPA only if restricted access is provided to the underlying data and models for independent validation by "authorized researchers." This approach, however, presupposes permission and participation from the

scientists doing the research. Since EPA does not have the authority to grant access to confidential and private research data, this approach would depend on the consent and approval of the scientists and institutions who conducted the research. It is unclear if this is at all possible, as researchers and institutions, in the example of many groundbreaking epidemiological studies, enter into contracts with participants to keep their health and other sensitive information private. It is improbable the researchers would or could alter these legal contracts after studies are concluded to allow individuals selected by EPA to gain access to such protected information, even in a tiered scheme. Thus, this approach would likely exclude many credible and valuable studies, including ones containing private information that EPA has benefited from in the past. It reinforces our ongoing serious concern that this proposal threatens the use of the best available science in its decision-making.

The second proposed tactic is a weighted approach model, i.e., if a study's data cannot be made publicly available for independent validation, it would be down-weighted in comparison to studies where data are publicly available. While incrementally better, the underlying concern remains. Saved from complete exclusion, this approach would still devalue research that is considered scientifically rigorous and could fundamentally benefit and shape public policy.

This model of down-weighting research maintains the major flaw in deeming data that cannot be made completely public – for legitimate and legal reasons to protect the privacy of health and confidential business information – less scientifically valid or valuable. It mischaracterizes the scientific process and the range of mechanisms for disclosing and protecting scientific research results for decision-making, implying that peer-reviewed scientific research data that are not available in its raw form is not rigorous enough for use in policy. This is simply not true.

We must emphasize that access to raw data is not determinative of the quality of the research. As has been stated by the scientific community repeatedly in response to this rule and now this supplemental, there are credible procedures for testing results and verifying outcomes with methodologies that do not require access to raw data. The original proposed rule and now this supplemental are de facto rejecting credible practices used by the scientific community and replacing them with a non-scientific metric in the evaluation of a study beyond its immediate quality. As the EPA's own Scientific Advisory Board has stated, this decision risks politicizing science by using an unscientific standard to assess the validity of science.

Moreover, we are deeply concerned that the supplemental expands the scope of the original rule to affecting not just studies underlying EPA's regulatory decisions but to all "influential scientific information." The supplemental defines this as any science the agency reasonably can determine will, or does have, a clear and substantial impact on important public policies or private sector decisions. This widening of the scope means that the rule won't just limit EPA's use of science underpinning regulation, but also EPA's use of science underpinning other significant outputs of the agency. The supplemental also expands the scope of studies that would be impacted by the revised rule, from the original proposed focus on only dose-response data and models to all data and models. With this expansion, the supplemental now risks limiting a massive breadth of scientific information because not all scientific data and models can be made public, as explained above.

For example, this drastic change means EPA will likely be unable to cite important studies on topics relating to the levels of contaminants in water, air and land; epidemiological studies that describe clinical markers of exposure or effect; and many other studies that are fundamental in understanding and protecting human health. That EPA would risk prohibiting or severely limiting such evidence and research sends a chilling message to the scientific community and risks breaching the confidence of the American public on whether they can trust EPA decisions to protect their health.

Lastly, the supplemental retains the troublesome provision that the EPA Administrator has sole authority to grant exceptions to the rule should he or she want to include a study that cannot meet the rule's standards. This kind of authority does not provide for proper checks and balances with appropriate scientific oversight bodies. Since EPA addresses a wide range of scientific disciplines that intersect environmental and public health policies, this exemption would eliminate the important role that scientific advisors play in the decision-making process.

Given the gravity of these concerns, which are echoed by a chorus of other scientific societies, health advocacy groups, universities, stakeholders, and member scientists of EPA's own Scientific Advisory Board, we urge the EPA to rescind this rule. This proposal would diminish the critical role of scientific evidence in helping to make decisions that impact the health of Americans. Excluding the best available science, as this proposal would, puts public health at risk.

Sincerely,

American Anthropological Association
American Association for the Advancement of Science
American Association of Geographers
American Chemical Society
American Economic Association Committee on Government Relations, Committee on Economic Statistics, and Office of the Data Editor
American Geophysical Union
American Institute of Biological Sciences
American Meteorological Society
American Physiological Society
American Psychological Association
American Society for Microbiology
American Society of Agronomy
American Sociological Association
American Statistical Association
Association of American Universities

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Crop Science Society of America
Ecological Society of America
Entomological Society of America
Geological Society of America
Harvard University
International Society for Environmental Epidemiology, North American Chapter
Massachusetts Institute of Technology
Mathematical Association of America
Research!America
Society for Freshwater Science
Society for Industrial and Applied Mathematics
Society of Wetland Scientists
Soil Science Society of America
Stony Brook University
University of California, Los Angeles
University of Colorado Boulder
Washington University in St. Louis